

FINAL REPORT ON THE STUDY OF PATIENT SAFETY IN MARYLAND

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I. Introduction

During the 2001 session, the Maryland General Assembly passed the "Patients' Safety Act of 2001," which charged the Maryland Health Care Commission (MHCC or Commission),¹ in consultation with the Department of Health and Mental Hygiene (DHMH), with studying the feasibility of developing a system for reducing the incidence of preventable adverse medical events in Maryland including, but not limited to, a system of reporting such incidents (see Appendix A).² A preliminary report was submitted to the Maryland General Assembly in January 2002. This final report outlines recommendations for developing a patient safety system in Maryland.

In conducting the study, the Commission was required to review federal reports and recommendations including two reports released by the Institute of Medicine (IOM) titled *To Err is Human* (1999) and *Crossing the Quality Chasm* (2001).³ In addition, the Commission reviewed the recommendations of national accrediting and quality assurance organizations, such as the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) and the National Quality Forum (NQF)⁴, as well as programs in other states and the best practices in hospitals and other health care facilities. The Commission's preliminary report included a thorough overview of the aforementioned reports and related initiatives in Maryland and other states.

Discussions of patient safety are difficult because of a lack of consistent terminology. Different agencies and organizations use similar terms, but define those terms differently. The Maryland Patient Safety Coalition and the subcommittees reviewed a variety of definitions including those used by the NQF, JCAHO and the Department of Veterans Affairs (VA) and agreed to standardize these terms. In this report, the terms "adverse event," "near miss," and "root cause analysis" are defined as follows:

"Adverse event" means an unexpected occurrence related to a person's medical treatment and not related to the natural course of the person's illness or underlying disease condition.

¹ The MHCC is a 13-member independent commission located administratively within the Department of Health and Mental Hygiene. The Commission is responsible for administering the provisions contained in the Health General Article §§ 19-101 through 19-141. The Commission was created in 1999 by combining the Health Care Access and Cost Commission (HCACC) and the Maryland Health Resources Planning Commission (MHRPC).

² Chapter 318 of 2001 (House Bill 1274).

³ Linda T. Kohn, Janet M. Corrigan, Molla S. Donaldson, eds., Institute of Medicine. *To Err is Human: Building a Safer Health System* National Academy of Sciences, 2000, and Committee on Quality of Health Care in America, Institute of Medicine. *Crossing the Quality Chasm: A New Health System for the 21st Century*. National Academy of Sciences, 2001.

⁴ The NQF is a private, non-profit voluntary consensus-driven standards settings organization that was established as a public-private partnership, and incorporated in May of 1999.

“Near Miss” is a situation that could have resulted in an adverse event but did not, either by chance or through timely intervention.

“Root Cause Analysis (RCA)” is a medical review committee process for identifying the basic or contributing causal factors that underlie variations in performance associated with adverse events or near misses.

In developing its recommendations, the Commission worked with the Maryland Patient Safety Coalition comprised of representatives from DHMH, the Delmarva Foundation for Medical Care (Delmarva), hospital and insurance industries, bodies representing organized physicians, nurses and pharmacists, as well as the State Boards of Health Occupations (e.g. licensing boards). Members of the Maryland General Assembly were also invited to participate.

Delmarva is the federally-designated Medicare Quality Improvement Organization (QIO)⁵, formerly known as the Peer Review Organization (PRO), for both Maryland and the District of Columbia. As such, Delmarva plays a significant role in quality improvement activities in the State. The Maryland Patient Safety Coalition serves as a sounding board for Commission's activities related to patient safety. Coalition meetings were held from June 2001 through November 2002. Further information on the Coalition's activities is provided in Section II, below.

Background

In 1999, the Institute of Medicine (IOM) released a landmark report on error in health care, *To Err is Human*, in which it was asserted that medical errors result in the deaths of approximately 44,000 to 98,000 Americans each year.⁶ As a result of this report, much attention and publicity was focused on the errors in health care settings.

The second IOM report, *Crossing the Quality Chasm*, addressed quality-related issues to an even broader degree than the first publication, providing a strategic direction for the complete redesign of the health care delivery system. Whereas *To Err is Human* was a call for action, *Crossing the Quality Chasm* called for a complete redesign of the health care system as we know it.⁷ The “chasm” refers to the gap that exists between today's medical system and an improved, higher quality system.

As a result of these reports, partnerships of business interests, such as the Leapfrog Group and other non-governmental organizations such as the National Patient Safety Foundation (NPSF),⁸ the JCAHO, the NQF, and others have developed patient safety data, information, and

⁵ QIOs are groups of practicing doctors and other health care experts. They are paid by the federal government to check and improve the care given to Medicare patients. They must review complaints about the quality of care given by: inpatient hospitals, hospital outpatient departments, hospital emergency rooms, skilled nursing facilities, home health agencies, Private Fee-for-Service plans, and ambulatory surgical centers.

⁶ Institute of Medicine. *To Err is Human*.

⁷ Institute of Medicine. *Crossing the Quality Chasm*.

⁸ The National Patient Safety Foundation (NPSF) was developed by the American Medical Association in response to the patient safety movement. The mission of the group is to improve patient safety through a core body of knowledge

recommendations to assist clinicians and educate the public on improving patient safety. Also, the National Academy for State Health Policy (NASHP)⁹ conducted an extensive review of state-level initiatives. To date, several Federal agencies have issued reports on patient safety recommending evidence-based practices, systemic reforms, and patient safety reporting systems.

Among the various initiatives undertaken in response to concerns over quality of care, the Department of Veterans Affairs' (VA) National Center for Patient Safety (NCPS) is among the most notable. The NCPS serves as a centralized location for the VA system's patient safety activities by encouraging the reduction and prevention of adverse events through the collection and analysis of aggregated data; providing education, feedback, and staff training; and investigating certain incidents to determine the source(s) of adverse events. This systematic approach to improving patient safety at all VA facilities has led to a cultural change and systems redesign, moving from a punitive environment to a more positive systems-based approach utilizing human factors engineering and safety theory to develop a culture based on learning.¹⁰ In addition, the VA's Patient Safety Reporting System (PSRS) is an externally-based system used to collect voluntarily reported data from health care staff. This system, separate from the NCPS, is also used to analyze reported incidents and identify system vulnerabilities.

In response to growing public attention over the reports on medical errors, other initiatives have been undertaken at the national and state levels within both the private and public sectors. Federal legislation has also been introduced during the last two years to improve patient safety in various settings; however, no bills have been enacted.¹¹

In addition, numerous state legislatures and regulatory agencies have instituted patient safety programs that recommend voluntary and/or require mandatory reporting of adverse events and near misses. Other states are studying the prospect of reporting such data. The National Academy for State Health Policy (NASHP), in its aforementioned review of state-level initiatives¹², reported that a universal definition of "medical error" and "adverse event" does not exist. Moreover, states with reporting systems differ in their use of the data and their handling of disclosure of the information, some maintaining it as confidential, others permitting or requiring

and pathways to apply that knowledge; improve the culture of awareness towards patient safety; and educate the public. <http://www.npsf.org>

⁹ NASHP is a non-profit, multidisciplinary forum designed to assist state health policy leaders from the executive and legislative branches on various health policy issues. NASHP conducts policy analysis, provides training and technical assistance to states, produces informational resources, and convenes state, regional, and national forums. <http://www.nashp.org>.

¹⁰ James P. Bagian, et al., "Developing and Deploying a Patient Safety Program in a Large Health Care System: You Can't Fix What You Don't Know," The Joint Commission Journal of Quality Improvement, October 2001. 27(10): 523.

¹¹ Patient Safety and Quality Improvement Act (S. 2590), Patient Safety Improvement Act of 2002 (H.R. 4889), Patient Safety Act of 2001 (S. 863), Patient Safety Act of 2001, (H.R. 1804), Medication Errors Reduction Act of 2001, (S. 824), Medication Errors Reduction Act of 2001, (H.R. 3292), Patient Safety and Health Care Whistleblower Protection Act of 2001, (H.R. 2340). The Patient Safety Improvement Act of 2002 (H.R. 4889) proposes voluntary reporting within the states. This bill recently passed out of the House Ways and Means Subcommittee. <http://www.thomas.loc.gov>.

¹² Jill Rosenthal, Trish Riley, Maureen Booth, National Academy for State Health Policy, State Reporting of Medical Errors and Adverse Events: Results of a 50-State Survey, April 2000.

disclosure. Mandatory reporting of serious adverse events is currently required in 20 states (see Appendix B).

Mandatory reporting systems and non-formal voluntary reporting exist in many states and are used as means to reduce medical errors. The IOM, in *To Err Is Human*, recommends a nationwide mandatory reporting system to collect standardized information about adverse events that result in death or serious harm. Mandatory reporting systems are generally designed to hold health care organizations accountable for patient safety and, in some instances, to inform the public. The collected data are used in most states primarily to identify trends, followed by issuing sanctions, assuring corrective action, and issuing public reports. While the current literature is replete with anecdotal information on the effectiveness of patient safety initiatives, there have been few systematic studies. Some speculation exists regarding the magnitude of events occurring versus those reported to state agencies under mandatory reporting systems. It is speculated that incidents are frequently underreported due to health care practitioners' fear of retribution, including criminal prosecution, lawsuits, job loss, or other punitive actions.

The initial IOM report also encourages voluntary reporting systems for systemic failures and near misses to identify problems before harm occurs. This voluntary system must be accompanied by a "blame-free culture" in which health care practitioners are not faulted for their actions or inactions when the incident was caused by a systems deficiency. It is critical to be aware that, as mentioned in the NASHP report, "...reporting systems are not ends unto themselves."¹³ The IOM report emphasizes that most errors occur because of system failures. It notes, however, that dangerous or reckless providers committing intentionally unsafe acts must be held accountable for their actions.

Systemic reform, or the improvement of those processes that affect the management of care (not that of an individual provider), has received much attention since the release of the second IOM report, *Crossing the Quality Chasm*. The IOM committee recommends that private and public purchasers of health care, health care organizations, clinicians, and patients should together redesign health care processes by focusing on systems that cause errors. The report states "the health care environment should be safe for all patients, in all processes, all the time."¹⁴

One method to improve patient safety within a health care environment encourages provider education. Provider training and continuing education coursework specifically addressing patient safety emphasize the importance of this issue and its relevance to the health care industry as a whole. Continuing education in patient safety is a method to change the thinking of health care practitioners to focus on systems-based approaches to patient care rather than individual acts. Another example is the use of a team-based approach to providing high-quality care. Care that is provided by a multidisciplinary and coordinated group of caregivers may offer the patient an integrated approach to treatment, providing a seamless system of care over time.

The use of information technology to improve systems has proven successful in many health care organizations; however, the cost to implement these systems has posed a barrier to many facilities. The Leapfrog Group has encouraged its participating health care organizations to

¹³ *Ibid.*

¹⁴ Institute of Medicine. *Crossing the Quality Chasm*.

implement computer-based physician order entry systems (CPOE) to help reduce the occurrence of medication errors.¹⁵ In New York, a coalition of large businesses has agreed to award bonuses to those providers that have instituted CPOE systems.¹⁶ The bonuses, in effect, act as a subsidy for the implementation of the system; however, the initial cost of implementing the system is assumed by the health care facility. While many organizations are very interested in this type of system, the expense of implementation is often financially prohibitive. Some facilities have sought to reduce costs by implementing CPOE incrementally.

Another approach to improving patient care is through the use of evidence-based practices. The Agency for Health Care Research and Quality has released an expansive list of evidence-based practices to the public.¹⁷ At the request of the federal government, the NQF has studied this list and has issued a “compendium of evidence-based safe practices.”¹⁸

The Department of Veterans Administration (VA)

Most stakeholders agree that the VA is a model for those health systems that want to improve patient safety. The \$20 billion VA is the nation’s largest integrated hospital and health care system. It includes 173 medical centers, approximately 800 outpatient clinics, 134 nursing homes, 206 counseling centers, and assorted other programs.¹⁹ The VA system employs 200,000 people, and more than three million veterans a year seek medical services at VA hospitals. A series of fatal medical errors at VA hospitals documented in the *St. Petersburg Times* (1997), followed by an internal report and a series of U.S. General Accounting Office reports that led to Congressional hearings, propelled the VA to action. The VA pledged to Congress that they would wage an all-out campaign against medical errors.²⁰ The VA’s efforts to uncover mistakes were aided by health care providers’ immunity from legal liability. Unlike malpractice claims against private providers, the United States government defends individual Veterans Administration practitioners acting within the scope of their employment.²¹ It is a protection that is missing from any state government attempting to replicate the VA program.

In 1998, the National Center for Patient Safety (NCPS) was created within the VA in an effort to improve the system of care through “processes that identify, prevent, and fix problems

¹⁵ Dagmara Sarudi, “The Leapfrog Effect,” *Hospital and Health Networks*, 75(5) May 2001.

¹⁶ Milt Freudenheim. “Companies Start Fund to Reward Hospitals for Better Care.” *The New York Times*. October 18, 2001.

¹⁷ The Agency for Healthcare Research and Quality (AHRQ) in July 2001, published a report, [Making Health Care Safer: A Critical Analysis of Patient Safety Practices](#), in collaboration with the University of California San Francisco/Stanford University. The publication includes 79 specific practices that contribute to safer patient care and validates each one according to current research. Out of 79 practices, 11 practices with the strongest evidence were rated as the most significant in terms of the strength of the evidence and received the authors’ support for more widespread implementation.

¹⁸ National Quality Forum (NQF), “Safe Practices” in Hospital Care.” NQF Project Summary, <http://www.qualityforum.org>.

¹⁹ The Veterans Health Administration. http://www.va.gov/About_VA/Orgs/VHA/index.htm.

²⁰ Lani Luciano, “Government Health System Leads the Way.” [Reducing Medical Errors and Improving Patient Safety: Success Stories from the Front Lines](#). The Institute for Healthcare Improvement and The National Coalition on Healthcare. February 2000.

²¹ Active duty members of the US Armed Forces cannot file a claim against the federal government under the Federal Tort Claims Act, however, their immediate family members can legally file suit.

that result in medical errors"²² within the facilities. The NCPS is strategically located within the VA to align with its "priority and importance," serving as a central repository for the collection of reported sentinel events, adverse events, and near misses.²³ The goals of the VA NCPS are targeted to create a culture of safety, emphasizing openness to reports of errors that occur, in order to locate vulnerabilities in the processes of care, and to prevent future errors. Key to this effort is the elimination of punishment for error reporting, thus permitting the identification of problems through the analysis of reported adverse events and near misses. The confidentiality of reported data is paramount to the success of this system. In addition, feedback to the reporter and other forms of communication addressing patient safety issues to the staff are essential to encourage staff participation and build trust in the system.²⁴

Staff employed in all VA health care settings are required to report "any unsafe conditions of which they are aware."²⁵ Sentinel events, adverse events, and near misses qualify for reporting to designated Patient Safety Managers (PSMs) within the facilities. The PSM uses a scoring methodology, known as the Safety Assessment Code or SAC, to determine if a root cause analysis (RCA) should be conducted. If a SAC score reaches a certain level of scope and severity, a multidisciplinary team conducts the RCA. The RCA process is an integral part of the VA's NCPS. As defined by the VA, an RCA is "a process for identifying the basic or contributing causal factors that underlie variations in performance associated with Adverse Events or Close Calls."²⁶ An RCA must not include negative descriptions of the cause and resulting effect of the incident and human error, in most instances, is not the underlying cause.

Two tools are used to aid the investigation – a computer-aided software tool ("SPOT") and a handheld guide for conducting RCAs (NCPS Triage Cards™ for RCA). The leadership of a VA facility, as well as the individuals who are familiar with the processes and systems under review, are required to participate in the RCA. An interdisciplinary team conducts the analysis of the RCA. In addition, each RCA is required to include corrective actions, outcomes measures, and top management approval.²⁷

Following the completion of the investigation, feedback on the findings is provided to the reporter of the event or near miss and a process for correcting the identified system vulnerabilities is outlined. At this point, with the exception of the facility name and date of the reported incident, the names of individuals involved in the studied event (patients and staff) are removed from the reports and related materials (e.g., the report is "de-identified") and the results of the studies are made available to the NCPS for widespread dissemination throughout the VA system. The recommended corrective actions are then presented to the involved facility's Chief Executive Officer (CEO) for approval and then implemented. The CEO can disapprove the recommended corrective actions and request the RCA team to identify other potential actions. When this is done,

²² Veterans Administration. "Veterans' National Center for Patient Safety is a Finalist in Prestigious American Government Award." Veterans Health Administration Highlights, Health Benefits and Services. September 7, 2001. <http://www.va.gov>.

²³ James P. Bagian, et al. "Developing and Deploying a Patient Safety Program in a Large Health Care System: You Can't Fix What You Don't Know." The Joint Commission Journal on Quality Improvement, 27(10), October 2001.

²⁴ Ibid.

²⁵ Department of Veterans Affairs, Veterans Health Administration, VHA Handbook 1050.1. January 30, 2002, p 6.

²⁶ Ibid., p 3.

²⁷ Ibid.

the original recommendations are retained in the RCA for the record. Follow-up is conducted by the facility to evaluate the effectiveness of the recommended actions.²⁸

Over 2000 health care professionals have participated in the intensive NCPS's RCA training, which covers three full days. Examples of hospital staff that have completed the training program include: risk managers, quality managers, patient safety managers, chief medical personnel, head nurses, and hospital directors. Hospital leadership is the target of this training so that a "culture of patient safety" is encouraged and those leaders will understand the benefits and foster the implementation of a non-punitive reporting system.

Following the introduction of the NCPS, the number of near miss incidents reported increased from a negligible amount to over 90% of all reported events (actual and potential) and the rate of adverse events reported increased by several hundred percent. Close calls (VA terminology for near misses) make up a majority of the incidents reported and are considered by many to be extremely beneficial in making changes to the system of care before an event actually happens.²⁹

The VA also has available an external reporting system, the VA Patient Safety Reporting System (PSRS). Developed in May 2000 in concert with the National Aeronautics Space Administration (NASA), the PSRS is a confidential, voluntary reporting system modeled after the aviation safety reporting system and managed by NASA. It is designed to encourage health care providers within the VA health care system to report adverse events and near misses to an external entity, in this case NASA. The PSRS began collecting reports in January 2002 and is presently disseminating information as 'case studies.' The PSRS is a three-year project costing \$8.2 million.³⁰

The VA has instituted many other patient safety initiatives designed to reduce medical errors. They include computerized medical records, bar coding, and provider continuing education requirements in patient safety. The VA health care system is replete with a wealth of patient safety-centered tools and instruments that are designed to improve quality of care and reduce medical errors.

While the VA system has been successful in encouraging a culture of patient safety, little is known about whether this system could be applied successfully to a state's entire health care system. Private health care institutions and national organizations, such as JCAHO, have adopted certain aspects of the NCPS. Moreover, while numerous states have implemented mandatory reporting systems in an effort to identify, analyze, and prevent adverse events, the success of such mandatory or voluntary reporting with feedback is still subject of debate. While many health care facilities and organizations have adopted patient safety as a goal, there is no clear consensus on the means to achieve it.

²⁸ James P. Bagian, et al, "Developing and Deploying a Patient Safety Program in a Large Health Care System".

²⁹ Veterans Administration. "Veterans' National Center for Patient Safety is a Finalist in Prestigious American Government Award." Veterans Health Administration Highlights, Health Benefits and Services. September 7, 2001. <http://www.va.gov>. Noel Eldridge. Presentation to the Office of Quality and Performance. The Department of Veterans Affairs Nation Center for Patient Safety. January 29, 2002.

³⁰ Veterans Administration. "VA to Develop No-Penalty, Medical Error Reporting System." Veterans Health Administration Highlights, Health Benefits and Services. June 2, 2000. <http://www.va.gov>.

The VA system can be characterized as a closed (or self-contained), top-down organizational structure, as opposed to an open, free market system. VA health care personnel are federal government employees whereas, in the private sector, most physicians are not employees of the facility or organization where they work. Many physicians, as well as other health care professionals, contract their services to a hospital, ambulatory surgical center, nursing facility, insurer, or health maintenance organization. The VA also has inherent civil protections for reporting as well as the resources to fund technological investments that are not available to most facilities in Maryland.

Joint Commission on Accreditation of Health Care Organizations (JCAHO)³¹

The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) is the nation's oldest and largest accrediting body for health care organizations. It accredits over 19,000 organizations that provide a wide range of health care services. The process by which hospitals and other health care facilities undergo accreditation by JCAHO involves announced triennial on-site surveys performed by surveyors who are qualified to evaluate an organization's compliance based on applicable standards that have been developed in consultation with health care experts. Surveyors evaluate compliance with each of the applicable standards using a five-point scoring scale.

Although accreditation by JCAHO is voluntary, hospitals that have it are considered as having "deemed status." The Centers for Medicare and Medicaid Services (CMS) deems any hospital that is JCAHO accredited as meeting the Federal certification requirements to qualify the hospital for Medicare and Medicaid reimbursement. Federal surveys of hospitals are limited to complaint investigations and rarely occur (only 1% of all hospitals annually). In Maryland, those facilities that are JCAHO accredited are 'deemed' by the OHCQ as meeting State licensure regulations. There are three State regulations, however, that hospitals must meet in addition to the JCAHO standards. They are requirements pertaining to physician credentialing, risk management and utilization review. Under State law, inspections are limited to surveys of these three programs, complaint investigations, and review of problems that have been identified by the State, CMS or JCAHO.

In the past two years, the OHCQ has worked closely with JCAHO to strengthen hospital oversight and ensure patient safety and quality care. In several instances, joint surveys were conducted at hospitals by both JCAHO and the OHCQ, with both entities working together to improve the hospitals' quality of health care delivery. In addition, all JCAHO reports (e.g., hospital surveys and complaint investigations) are reviewed by the OHCQ.

In 1996, JCAHO created a hospital "sentinel event" reporting system. Sentinel events subject to reporting are those that have resulted in an unanticipated death or major permanent loss of function not related to the natural course of the patient's illness or underlying condition, or an event that meets the following criteria (even if the outcome was not death or major permanent loss of function): (1) suicide of a patient in a setting where the patient receives around-the-clock care; (2) infant abduction or discharge to the wrong facility; (3) rape; (4) hemolytic transfusion reaction

³¹ Joint Commission on Accreditation of Healthcare Organizations. <http://www.jcaho.org>.

involving the administration of blood or blood products having major blood group incompatibilities; or (5) surgery on the wrong patient or wrong body part. JCAHO requires that a hospital that experiences a sentinel event conduct a root cause analysis (RCA), a process for identifying the basic or causal factor of the event that underlies variation in performance. An RCA focuses primarily on systems and processes, not the performance of an individual. It progresses from special causes in clinical processes to common causes in organizational processes and identifies potential improvements that would tend to decrease the likelihood of such events in the future, or determines, after analysis, that no such improvement opportunities exist. The product of the root cause analysis is an action plan that identifies the strategies that the organization intends to implement to reduce the risk of similar events occurring in the future.

Accredited hospitals are encouraged, but not required, to report to JCAHO any adverse event that meets the above criteria and to submit the root cause analysis. If a hospital reports to JCAHO, JCAHO may accept the hospital's root cause analysis as an appropriate response and JCAHO may choose not to pursue any further action. If the hospital does not report a sentinel event and JCAHO becomes aware of it through a complaint, the media, or another manner, JCAHO may conduct an unannounced on-site survey. If the hospital has not conducted a root cause analysis or if the root cause analysis is not adequate, the hospital may be at risk to lose its accreditation status. JCAHO publishes a newsletter that identifies particular sentinel events (*The Sentinel Event Alert*). Information regarding the events' causes and methods to prevent their occurrences are described.

After the release of the 1999 IOM report and the renewed interest in patient safety on the national level, JCAHO developed new Patient Safety and Medical Error Reduction Standards for all accredited hospitals. These new requirements, which became effective July 1, 2001, require accredited hospitals to provide a safer environment for hospital patients through an internal hospital-wide occurrence (anything from a "slip or near-miss" to a sentinel event) identification, reporting, evaluation, and corrective action process. JCAHO requires specific mechanisms for determining the severity of an occurrence, mechanisms for the level of response to an occurrence including care of the affected patient, containment of risk and preservation of factual information for subsequent analysis, and notice to patients and families when an incident occurs. In addition, leadership within the facility is required to create a culture of safety. JCAHO will release similar standards in January 2003 for behavioral health care and long-term care organizations, followed by ambulatory surgical facilities and home care organizations in 2004.

As part of its continuing patient safety commitment, JCAHO released this past summer its National Patient Safety Goals. The six goals make up the first set of goals in a series to be released each year. As part of the initial set of six goals, the *Sentinel Event Alert* Advisory Group developed 11 recommendations based on previous *Alert* recommendations (see Appendix C). These recommendations will be included in the survey process beginning in January 2003. Hospitals will be cited for violations if these recommendations (or approved alternatives) are not implemented.

The Leapfrog Group

The Leapfrog Group is a consortium of approximately 80 Fortune 500 companies and other large private and public health care purchasers. In November 2000, the Leapfrog Group initiated a national effort to recognize and reward providers for advances in patient safety and to educate employees, retirees, and families about the importance of hospitals' efforts in this area. The Group's current focus on improving patient safety is tailored to three areas: computerized physician order entry (CPOE); referral of patients with certain complex conditions to hospitals proven to provide better care (evidence-based hospital referral); and staffing of intensive care units with intensivists, physicians who specialize in the care of critically ill patients.

Participation in The Leapfrog Group is on a voluntary-basis; however, members must agree to certain purchasing principles³² –

- Inform and educate employees on selecting and evaluating the performance of a provider;
- Develop comparative value ratings to evaluate providers using sources such as NCQA, JCAHO, and state information;
- Use substantial incentives to influence and reward delivery systems that have 'higher value ratings' by encouraging consumers to receive treatment at high-performing facilities (directing patient volume), varying payment (such as bonuses) for superior care based on comparative ratings, and through recognition of facilities that exhibit superior performance;
- Focus on discrete forward leaps in patient safety that yield improvements in health care delivery (CPOE, evidence-based hospital referral, and ICU physician staffing);
- Hold health plans accountable for Leapfrog implementation of the aforementioned principles; and
- Encourage the support of consultants and brokers through incentives to use the purchasing principles.

In addition, the Leapfrog Group has certain requirements for each of the three safety measures that hospitals must meet.³³ They are as follows:

- CPOE – Hospital computer systems must link to software which prevents prescribing errors. Physicians are required to enter medication orders directly into this system. Hospitals must demonstrate that, through their system, at least 50% of serious prescribing errors are identified (or intercepted), and that those physicians who become aware of a prescribing error must provide documentation acknowledging it.
- Evidence-based Hospital Referral – Participating members in the Leapfrog Group are recommended to encourage their employees, retirees and family members who will undergo elective treatment to obtain their care at hospitals that have high volume

³² The Leapfrog Group, LeapfrogPurchasers, Purchasing Principles, <http://www.leapfroggroup.org/purchase1.htm>

³³ The Leapfrog Group, Patient Safety, <http://www.leapfroggroup.org/safety1.htm>

procedures for which scientific evidence exists of a positive relationship between volume and outcome for certain specific high-risk conditions.³⁴

- Intensive Care Unit (ICU) Physician Staffing – Leapfrog defines intensivists as physicians certified (or eligible for certification) in critical care medicine. The requirements for this standard are that patients in adult general medical and surgical ICUs are managed or co-managed by physicians who are certified in critical care medicine and (1) are present in the ICU during daytime hours (minimum 8 hours per day, 7 days per week) and provide care exclusively in the ICU; or (2) are able to return pages (95% of the time) within five minutes and can rely on in-hospital physicians or Fundamental Critical Care Support (FCCS)-certified physician extenders for immediate care.

Congressional Action

Several bills have been introduced in both the U.S. Senate and the House of Representatives related to patient safety; however, none of these bills has passed. The 106th Congress was responsible for approximately six bills pertaining to patient safety issues. The 107th Congress introduced 15 bills. Among the subjects of these bills were the description and requirements of various reporting systems; the establishment of a patient safety center within the Agency for Healthcare Research and Quality (AHRQ); informatics grant programs to hospitals and skilled nursing facilities; the public disclosure of clinician staffing and performance or outcomes data; the provision of programs to improve nurse retention; and provisions to limit the number of mandatory overtime hours a nurse may be required to work.

House Bill 4889, the ‘Patient Safety Improvement Act,’ and House Bill 2598, the ‘Patient Safety and Quality Improvement Act,’ recently passed out of their respective committees and are currently being reconciled. Both bills would establish voluntary, non-punitive, confidential reporting systems with patient safety organizations (PSOs) serving as the recipients of provider reports detailing adverse events and near misses. The PSOs would also analyze and disseminate data to reduce the occurrence of adverse events. Data that are collected and reported to a PSO are afforded protections from liability and discovery as the information will not be subject to civil or administrative subpoena or order; subject to discovery; subject to disclosure under the Federal Freedom of Information Act; or admitted as evidence in a proceeding. In addition, whistleblower protections are provided. More detailed information on specific Federal Senate and House bills is provided in Appendix D.

Patient Safety Activities in Maryland

The range of patient safety efforts in Maryland is quite diverse - some health care facilities have instituted comprehensive patient safety programs while others maintain only basic risk management plans.

³⁴ The procedures are: Coronary artery bypass; coronary angioplasty; abdominal aortic aneurysm repair; carotid endarterectomy; esophageal cancer surgery; delivery with expected birthweight <1500 grams or gestational age < 32 weeks; and delivery with pre-natal diagnosis of major congenital anomalies. The Leapfrog Group Factsheet: Evidence-based Hospital Referral (EHR), November 2000, http://www.leapfroggroup.org/FactSheets/EHR_FactSheet.PDF.

As described in last year's Interim Report, the Maryland Patient Safety Coalition developed and conducted a survey in 2001 to capture information on hospitals, nursing homes, provider and industry associations, and the current activities of the State health occupation Boards related to patient safety. For those facilities that did not respond to the initial request for information, a follow-up survey was conducted in early 2002. An analysis abstracted from a survey of Maryland hospitals indicates that health care facilities and organizations have undertaken various initiatives aimed at improving patient safety and reducing adverse events. Many of the organizations, especially hospitals, have instituted a variety of projects, ranging from patient safety task forces to medication error reduction activities. Over half of the hospitals and long-term care facilities responding to the survey indicate that a self-assessment has been conducted within the organization to identify processes that need to be improved. A majority of the patient safety activities listed by hospitals are aimed at preventing falls, improving medication safety, and implementing patient safety plans and policies. Specific examples of patient safety activities initiated by hospitals include medication-error prevention processes such as removing dangerous drugs from patient care units, the use of special packaging and labeling of high risk drugs, and bar coding of medications and patient identification bracelets. Also, several hospitals have formed task forces to analyze patient safety issues as well as specific clinically related areas of high risk, such as nosocomial (hospital-acquired) infection rates.

Among long-term care facilities, activities range from risk management projects, such as implementing a plan to prevent patient falls, to establishing quality assurance/quality improvement programs where none existed, and medication error reduction programs. One facility listed a medication error reporting system as an initiative, while another facility has a 'zero-accident culture' safety committee. Many of the long-term care facilities that responded to the survey indicate a strong focus of their leadership in identifying, monitoring, and analyzing adverse events. Efforts to improve patient safety and quality of care have also been initiated through the State's Office of Health Care Quality (OHCQ) and the federal Centers for Medicare and Medicaid Services (CMS) contracting Quality Improvement Organization (QIO) in Maryland (Delmarva). The OHCQ recently implemented a technical assistance survey to assist nursing home staff with quality assurance activities, and has facilitated a quality assurance coordinator group to discuss and encourage the adoption of quality improvement projects proven effective at improving resident care. Maryland was also one of the six states chosen by CMS to participate in a pilot project to expand public reporting of quality measures for nursing homes and to promote specific quality initiatives across nursing homes through projects sponsored by the Maryland QIO. Examples of quality initiatives are reductions in pressure ulcers (bedsores) and improved pain management.

In terms of technology reported in the survey, only two of the state's acute care hospitals have computerized physician order entry (CPOE) and only one has a bar coding system in place to identify and reduce medication errors. A small number of facilities indicated that they are in the process of implementing these systems.³⁵ Over half of the Maryland acute care hospitals indicated that intensivists are currently used to manage ICUs (56% of respondents). Many of the responses from the hospitals indicate that CPOE, bar coding, and simulation (of potential errors) have been discussed; however, implementation of these programs has not occurred. Many of these initiatives are expensive to implement, even in a single facility. While the initial cost of implementing these

³⁵ Ten hospitals indicated that CPOE is currently being implemented and 3 facilities are installing barcoding technology

projects is relatively large, it has been argued that the amount of money saved by reducing adverse events and patient length of stay, as well as increasing the number of lives saved, far outweighs the costs of implementing these projects.

To date, the initiatives undertaken by Maryland hospitals and long term care facilities appear to lack focus. For example, educational programs aimed at orienting new employees or staff members to a facility's patient safety plan or policies are conducted by only a few facilities. The sharing of "best practices" is only fostered by a few facilities as well. While the implementation of the various patient safety activities among the Maryland facilities is particularly noteworthy, an overall goal or policy among many of the facilities does not appear to be present.

State Legislation

Several pieces of legislation enacted during the 2002 General Assembly session affect patient safety in health care settings. First, a bill that prohibits involuntary overtime for nurses became law.³⁶ Employers may not require a nurse to work more than the regularly scheduled hours according to the predetermined work schedule. However, in some instances (e.g., emergency situations), nurses may be required to work overtime.

Second, a bill was introduced to move the medical review committee provisions that apply to all health care practitioners from the Board of Physician Quality Assurance (BPQA) statute, where they had been codified, to a subtitle within the Health Occupations Article that governs all health occupations. This was proposed in an effort to make practitioners more aware of the protections available to them. It also codifies case law to clarify that certain good faith communications designed to lead to remedial action are protected even when they are not made directly to a medical review committee or committee member, but are nevertheless designed to remedy a problem under the jurisdiction of a medical review committee.³⁷

Third, the Health Care Worker Whistleblower Protection Act passed.³⁸ This Act prohibits an employer from taking or refusing to take personnel action as a reprisal against an employee who discloses or provides information to a supervisor or board regarding a violation of a law, rule, or regulation.

Other Maryland Activities

Maryland Hospital Association (MHA): In January 1999, the MHA expanded its vision for quality in health care by embarking on programs to focus on safe practices. A key component of this vision is to reduce the frequency of unsafe practices that can be quantified through performance measures. Consequently, the MEDSAFE initiative was launched as a three-year statewide approach to understanding salient practices among Maryland hospitals. The initial focus of the MEDSAFE was on medication-use patterns and their implications for patient safety. All

³⁶ Chapter 322 of 2002 (Senate Bill 537).

³⁷ Chapter 158 of 2002 (Senate Bill 421).

³⁸ Chapter 504 of 2002 (House Bill 329).

Maryland hospitals were invited to participate and use the new information internally for performance improvement.

During the first year of the project, a new database was created on the various activities in place across Maryland hospitals. A representative sample of 14 hospitals voluntarily completed a survey tool designed by MEDSAFE, and this new information established a baseline among Maryland hospitals on internal environments, safety culture, and information technology capabilities.

In the second year, through a partnership established between MEDSAFE and the Institute for Safe Medication Practices (ISMP), ISMP's nationally tested self-assessment tool was made available to all Maryland hospitals. All Maryland hospitals completed the 194 questions on the ISMP tool and reported them to MHA. All the data were stored within MHA's Center for Performance Sciences (CPS) with hospital identifying information removed. A comprehensive analysis of this newly created database was performed by CPS and, in October 2002, each participating hospital received a report relative to their completed survey, as well as a comparative analysis on how other facilities are doing. Further, MHA has provided ongoing education to hospital leadership to make patient safety monitoring an ongoing culture across Maryland hospitals. A special issue of *Maryland Health Care* will profile some Maryland hospitals that are enhancing their patient safety practices.

A statewide meeting is planned for all participating Maryland hospitals (January 2003). The goal of this meeting is to reach consensus on the establishment of better practice models for the state.

All the data collected and analyzed through MEDSAFE are kept confidential and are aimed at helping Maryland hospitals use the new knowledge to internally improve performance. MEDSAFE is carried out by CPS staff under the guidance of an Advisory Panel. It is expected that after Year Three, MEDSAFE will become an ongoing service to Maryland hospitals by the MHA similar to its Quality Indicator Project (QIP).

The Maryland Board of Pharmacy: The Board of Pharmacy has proposed regulations that: define "high-alert medication" and a "medication error;" require pharmacies to establish methods to educate patients in preventing medication errors; require pharmacies to ensure that every staff person involved in the delivery of medications receives, at least once annually, education regarding medication error prevention; and require pharmacies to establish and maintain a quality assurance program. In addition, legislation passed during the 2002 General Assembly session grants medical review committee status to pharmacies. This status enables those individuals who report information through the quality assurance program and the accompanying materials to have protections against discoverability and liability.

The Maryland Board of Nursing (MBON) is exploring the feasibility of conducting a pilot study with the MHA to determine if a confidential remedial program that assists a licensed nurse who has been recognized as committing a practice or medication error or has a clinical practice concern increases reporting and enhances patient safety. Called the 'Practitioner Remediation and Enhancement Partnership' or PREP program, its focus is to create a program that provides a non-

punitive alternative to discipline for the at risk nurse or the nurse who has created a practice error by developing remediation, if needed, and identifying at risk patterns of practice. Initially, a nurse is advised of his/her deficiencies, and then an individualized remedial program is developed. The program is monitored for the nurse's improvement in the identified practice areas. An advisory committee was formed to develop the program components and includes a nurse executive, human resources representative, Board of Nursing member, nurse manager, quality assurance representative, MBON staff, MHA representative, and Board attorney.

Through participation in the program, the nurse may be able to continue working for the health care entity and eliminate a notice of discipline on his/her license. Other goals of the program are to strengthen the overall practice of the nurses and to identify problems early.

II. Maryland Patient Safety Coalition

As part of the enabling legislation, the MHCC is required to review patient safety initiatives in consultation with the Department of Health and Mental Hygiene (DHMH). In developing its preliminary recommendations, the Commission worked with the Maryland Patient Safety Coalition comprised of representatives from DHMH, the Delmarva Foundation for Medical Care (Delmarva), hospital and insurance industries, bodies representing organized physicians, nurses and pharmacists, as well as the State Boards of Health Occupations (e.g. licensing boards). Members of the Maryland General Assembly were also invited to participate.

The Delmarva Foundation is the Medicare Quality Improvement Organization [QIO – formerly known as the Peer Review Organization (PRO)] for both Maryland and Washington, D.C. As such, Delmarva plays a significant role in quality improvement activities in the state. The Maryland Patient Safety Coalition serves as a sounding board for the Commission's activities related to patient safety. Coalition meetings were held from June 2001 through November 2002.

Summary of Coalition Activities

Several recognized leaders in patient safety were invited to speak to the Coalition. These individuals represent key organizations that have programs or initiatives that are geared towards the delivery of safer health care. In addition, the Coalition focused its activities in 2002 on three areas that were determined to be crucial to the success of a patient safety plan: regulations; systems change; and the creation of a Maryland Patient Safety Center. Described below are selected excerpts from the Maryland Patient Safety Coalition meetings. These selections encompass key points discussed during the meetings.

(A) Featured Speakers –

James P. Bagian, M.D., P.E., Director, National Center for Patient Safety, Department of Veterans Affairs, Veterans Health Administration

Dr. Bagian spoke about the Veterans Administration's (VA) National Center for Patient Safety (NCPS) and its purpose to promote a system of safety that is led by a patient safety culture, emphasizing prevention of errors and not punishment for error reporting, and locating vulnerabilities in the processes of care that are identified through the reporting of adverse events and near misses (or 'close calls'). The NCPS is responsible for training individuals in contributing factor and root cause analysis (RCA) of adverse events and near misses. To date, over 2000 health care professionals have participated in the intensive RCA training, covering three full days.

Data that are reported to the NCPS are confidential. Patient safety information is shared with staff; results from an investigation are provided to the reporter and other forms of communication addressing patient safety issues are distributed to the staff. The NCPS system promotes learning and education of methods to reduce the occurrence of adverse events and near misses instead of focusing on accountability. To that end, events that are considered 'intentionally unsafe acts' by the VA (such as a criminal act) are not evaluated through the NCPS, but are reported to a facility director.

Kenneth Kizer, M.D., President and C.E.O., National Quality Forum (NQF)

Dr. Kizer, former Under Secretary for Health in the U.S. Department of Veterans Affairs, spoke of the NQF's project - 'Serious Reportable Adverse Events in Healthcare: A Consensus Report' (see Appendix E). This list of 27 serious reportable events was developed in an effort to define preventable, adverse events that should never occur, and that can be used by the states to collect a standardized set of measures. According to Dr. Kizer, the list was developed primarily to "[identify] a standardized set of serious reportable events in healthcare...to facilitate public accountability for the occurrence of these adverse events and to reduce their occurrence."³⁹ The list meets certain criteria identified by the NQF as unambiguous, usually preventable, and serious. These events can also be adverse, and/or indicative of a problem in a health care facility's safety systems, and/or important for public credibility or public accountability.

The NQF is a private, non-profit voluntary consensus-driven standards settings organization. Established as a public-private partnership, and incorporated in May of 1999, the NQF has a broad participation from all parts of the health care sector, including national, state, regional and local groups representing consumers, public and private purchasers, health care professionals, providers and plans, accrediting bodies, supporting industries, and health care research and improvement organizations. Its primary focus is to standardize the measurement of data relating to quality and safety in health care; to design a strategy and framework for a National Healthcare Quality Measurement and Reporting System; and to promote, guide, and lead health care quality improvement. The NQF's projects include hospital care performance measures, diabetes care performance measures, and cancer care performance measures.⁴⁰

The NQF and NASHP recently introduced the SAFER project. SAFER is the acronym for 'State Alliance for Error Reporting.' The intent of this project is for interested states to pilot the collection of the serious reportable events. At the present time, NASHP is comparing this list to those events that are required to be reported in those 20 states that have mandatory reporting systems (<http://www.qualityforum.org>). See Appendix B for a list of states that require reporting of certain events to a state agency. Representatives from states that require hospital staff (as well as other medical facilities) to report certain events to a designated state agency are participating in this project with the NQF and NASHP. Although Maryland does not currently mandate error reporting, it has participated in the SAFER meetings and is part of the Alliance.

Karen Wolk Feinstein, Ph.D., President of the Jewish Healthcare Foundation of Pittsburgh, PA - Pittsburgh Regional Health Care Initiative (PRHI)

Similar to the Leapfrog Group, the PRHI was formed to improve health care delivery in Pittsburgh through specific initiatives. The coalition was formed under the leadership of Paul O'Neill, the former chairman of Alcoa, an aluminum manufacturer. The coalition includes 35 hospitals, four insurers, and over 30 large and small health care purchasers.⁴¹ The coalition focuses on improving the health care delivery system by improving outcomes in five areas: cardiac

³⁹ Kenneth Kizer, M.D., M.P.H, President and CEO, The National Quality Forum, presentation to the Maryland Patient Safety Coalition, October 10, 2002.

⁴⁰ Ibid.

⁴¹ <http://www.prhi.org/coalition/coalition.htm>.

surgery; hip and knee replacement surgery; repeat cesarean sections for women at low risk; depression; and diabetes. In addition, PRHI's aim is to reduce hospital-acquired (nosocomial) infections and medication errors to zero. Data on medication errors are collected through MedMARx™, a proprietary data tracking system developed and maintained by U.S. Pharmacopeia (see below). Nosocomial infection data are tracked through the National Nosocomial Infection System with assistance from the federal Centers for Disease Control.

These data will be used to benchmark each hospital's improvement in outcomes over time. In support of this initiative, The Robert Wood Johnson Foundation has contributed a \$1 million grant.⁴²

Diane Cousins, Vice President for the U.S. Pharmacopeia Center for the Advancement for Patient Safety, and Jennifer Devine, Assistant Legal Counsel, U.S. Pharmacopeia

United States Pharmacopeia (USP) is a non-profit, volunteer-based, private organization that works closely with health care practitioners and institutions, regulatory agencies, professional organizations and the pharmaceutical industry to provide education about patient safety. The goals of USP's Patient Safety Program are to: increase practitioner awareness of medication errors and methods of prevention; examine and evaluate the causes of medication errors and propose standards; develop the information, tools, and strategies needed to make good decision; and conduct research and build partnerships to reduce medical errors.⁴³

USP's MedMARx™ Program is a proprietary, Internet-based, anonymous, interactive medication error prevention tool that enables hospitals using it to report and track medication errors in a standardized format. Over 500 hospitals across the country have subscribed to this program, including the U.S. Department of Defense, the U.S. Department of Veterans Affairs, and many community and teaching hospital facilities.⁴⁴ The system allows the participating facilities to report medication errors anonymously, to retrieve data and analyses about their own facility, and to obtain non-identifiable comparative information on other participating hospitals. An e-mail system allows communication between users and USP, while still maintaining anonymity through the use of a unique numerical facility identifier. USP can issue alerts to a single user or a group. Another feature of the MedMARx™ system is that it also provides a template for JCAHO's model for conducting a root cause analysis.

In 1991, USP began operating the Medication Errors Reporting (MER) Program with the Institute for Safe Medication Practices. This program, which is confidential, provides health care practitioners and other stakeholders with an on-going, national voluntary mechanism for reporting actual or potential medication errors. USP reviews each report it receives and then forwards all information to the FDA and the respective product manufacturer.⁴⁵ Since its inception, over 7,000 reports of actual and potential medication errors have been submitted to the program.⁴⁶

⁴² Jane-Ellen Robinet. "Pittsburgh's Health Care Initiative in National Spotlight." Pittsburgh Business Times. <http://pittsburgh.bcentral.com>. May 31, 2001.

⁴³ Presentation by Diane D. Cousins, R. Ph. and Jennifer Devine, J.D., U.S. Pharmacopeia, to the Maryland Patient Safety Coalition.

⁴⁴ U.S. Pharmacopeia's Patient Safety Initiatives Fact Sheet, May 2002.

⁴⁵ <http://www.usp.org/reporting/mer.htm>.

⁴⁶ U.S. Pharmacopeia's Patient Safety Initiatives Fact Sheet, May 2002.

(B) Subcommittees –

The Maryland Patient Safety Coalition formed three subcommittees to focus on the previously identified areas of interest. These subcommittees each met several times in addition to the full Coalition meetings.

Maryland Patient Safety Center Subcommittee

This subcommittee was co-chaired by Barbara McLean, Executive Director of the MHCC and Michael Preston, Director of MedChi. See Appendix F for a list of members. The creation of an entity to act as a recipient of voluntary reports reflecting adverse events and near misses, as a clearinghouse of information, and as a leader in patient safety education was seen as a key component to the success of a patient safety system in Maryland.

The recommendations of this subcommittee are presented in Section III – Proposed Comprehensive Patient Safety System for Maryland.

Health Care Systems Subcommittee

Enrique Martinez-Vidal, Deputy Director for Performance and Benefits at the MHCC, chaired this group that reviewed the role of technology and other initiatives used to reduce the occurrence of adverse events. Topics include high-tech, expensive interventions, such as computerized physician order entry and electronic medical records, as well as short-term, low-cost recommendations to reduce the likelihood of a medical mistake, such as removing a dangerous drug from a hospital patient care unit.

See Appendix G for a list of members. The recommendations of this subcommittee are presented in Section III – Proposed Comprehensive Patient Safety System for Maryland.

Revision of Regulations Subcommittee

The Interim Report on Patient Safety recommended that OHCQ review the Risk Management regulations and strengthen the requirements based on recommendations of the Maryland Patient Safety Coalition, current JCAHO Standards and current Patient Safety expertise. The workgroup was led by Carol Benner, Director of the OHCQ. Appendix H includes a list of participants.

The recommendations of this subcommittee are presented in Section III – Proposed Comprehensive Patient Safety System for Maryland.

III. Proposed Comprehensive Patient Safety System for Maryland

Overview

In 2002, the Maryland Patient Safety Coalition established three subcommittees, referenced above, to address key areas of patient safety: (1) **patient safety center subcommittee** – this group discussed the key features of a patient safety center to be developed to serve as a repository for information about adverse events voluntarily submitted by providers and to provide certain educational activities; (2) **systems issues subcommittee** – this group reviewed certain structure and process initiatives that could be used by facilities to reduce adverse events, and how they could be encouraged; and (3) **regulatory subcommittee**– this group focused on revising the current risk management regulations to create patient safety reporting systems within hospitals and to mandate reporting of certain sentinel and serious adverse events to Maryland’s Office of Health Care Quality.

The Commission is proposing a three-pronged approach as the foundation for a patient safety system in Maryland (see Diagram A). These three components, while mutually exclusive, serve as the basis for recommendations for a comprehensive patient safety system in Maryland.

A. Maryland Patient Safety Center

The Coalition members agreed that the creation of a Maryland Patient Safety Center (MPSC) should be the centerpiece of Maryland’s patient safety initiative. Its purpose is to foster the creation of safety cultures within health care institutions and among providers and users of the state’s health resources, to identify and determine the causes of adverse events and near misses, and also to educate hospital and nursing facility administrators and health care professionals in the processes that reduce the future occurrences of adverse events. In many respects, the MPSC will attempt to replicate the VA model of patient safety, which has proven successful in educating health care workers in methods to understand how adverse events can occur and develop strategies to reduce them. A keystone of this effort is the encouragement of non-punitive and non-blaming attitudes, so that real and potential errors will be willingly reported, thus contributing to the prevention of future errors.

The Patient Safety Center would support the collection of voluntary de-identified reports on adverse events and near misses. The University of Maryland, Baltimore (as the principal investigator), along with the MHCC and the Delmarva Foundation, applied for a health services research grant to create the Maryland Patient Safety Center (MPSC). This grant is offered by the federal Agency for Healthcare Research and Quality. The Maryland Hospital Association would serve as consultants on the project. The specific question to be addressed by the proposed research is whether Maryland can develop, within a health care delivery system without clear lines of authority, a comprehensive, systems-focused patient safety program that encourages broad participation in a voluntary reporting environment of adverse events and near misses. The proposed demonstration project tests a model for building grassroots consensus around the importance of adverse event identification and reporting, provider education, and dissemination of recommended clinical and organizational ‘better practices’ (see Diagram B).

The overall goal of this demonstration project is to explore the feasibility of improving patient safety in the state of Maryland through the establishment of a unique and novel patient safety center that will serve as a data repository for a voluntary adverse event and near miss reporting system and will result in the following: enhanced adverse event and near miss problem identification in Maryland hospitals and nursing homes; and a novel and unique system to educate health care providers.

The grant will focus on four major aims:

(1) Creation of the Maryland Patient Safety Center (MPSC)

The Center for Health Policy/Health Services Research, the University of Maryland, Baltimore's (UMB) Health Policy Organized Research Center (ORC), a public academic setting, will serve as the data repository center for voluntarily reported adverse events and near misses and as the primary coordinator for educational activities related to building consensus around patient safety issues.

(2) Education of Health Care Professionals and Hospital Administrators

The MPSC will provide an innovative and novel approach to reducing health care related adverse events and near misses by implementing an education and training program for targeted health care professionals and hospital administrators⁴⁷, teaching them a method of research and analysis of the causes of adverse events and near misses in order to eliminate system vulnerabilities (root cause analysis or "RCA"). State regulations that will prioritize the adverse events and near misses on which hospitals must perform RCAs and outline what actions must be taken by facilities in response to the RCA findings will be proposed (see Appendix I). In addition, those practices identified as reducing the occurrence of adverse events and improving quality of care (better practices, relevant peer-reviewed literature, and the results of RCAs) will be analyzed and disseminated, as appropriate, to hospitals and nursing homes.

Hospitals and nursing homes are the targeted institutions for this demonstration project and are selected because of their leaderships' and staff's familiarity with data collection procedures and tools. The institutions also are currently engaged in institution-specific patient safety activities. For example, Maryland is one of six states involved in a CMS pilot project for nursing homes that involves specific activities to improve patient care to reduce pressure ulcers (bedsores) and falls. Recently, Maryland was chosen to be one of three states to participate in the CMS pilot project for hospital performance reporting. Further, the Maryland Hospital Association has a patient safety committee which is targeting quality improvements.

(3) Collection and Analysis of De-identified Adverse Event and Near Miss Information

Data solely on adverse events and near misses from which identifying information has been removed (de-identified) will be collected voluntarily from participating hospitals and nursing homes. Those adverse events and near misses voluntarily reported to the MPSC by hospitals and

⁴⁷ Examples of hospital staff that would participate in the training program include: risk managers, quality managers, patient safety managers, chief medical personnel, head nurses, and hospital directors.

nursing homes will be analyzed to determine the geographic locales in which they occur, the prevalence rates of these events, in which types of facilities they tend to occur, and which types of providers are involved. Because the reports will be made to an academic center independent of the state licensing authorities, the emphasis on learning will encourage reporting. There will be, in effect, a “firewall” between the state licensing authority and the MPSC’s voluntary reporting system.

To further encourage reporting, it is recommended that Maryland statute be amended to grant civil immunity status to the MPSC as a medical review committee. Individuals or institutions that report adverse events and near misses must be able to convey this information to the Center without fear of legal discoverability, litigation, or medical malpractice. Lacking such protection, it seems clear from other studies that willingness to voluntarily report will be significantly reduced, possibly affecting the success and even the viability of the MPSC.

(4) Development and Implementation of a Grassroots Model for Building Consensus

The development and implementation of a grassroots model for building consensus to promote a culture of patient safety in Maryland health care institutions is a novel and innovative aspect of this demonstration project.

An Advisory Board will be created to assist the University of Maryland’s (UM) Organized Research Center (ORC) in the analysis of the aggregated reported events and in the identification of practices that appear to reduce adverse events and near misses (“better practices”). The Advisory Board will consist of representatives from health care industry associations, healthcare professional societies and associations, the Quality Improvement Organization (Delmarva Foundation), the Maryland Health Care Commission, and other organizations that are interested in and committed to improving patient safety in Maryland health care settings. The Advisory Board will encourage hospitals and nursing homes to participate in the voluntary reporting and educational activities of the Center. In addition, the Advisory Board will develop a process for using this information to determine priorities in patient safety improvement. The provider community (i.e., individual facilities and practitioners), professional societies and associations, and industry association members of the Advisory Board will facilitate the dissemination of the recommended practices.

Summary of Aims: The creation and operation of the MPSC will fulfill a priority identified in the federal AHRQ Health Services Research grant announcement that encourages demonstration projects to improve quality of care and patient safety within health care systems. This proposal involves the creation of MPSC to identify and determine the causes of adverse events and near misses in hospitals and nursing homes, and also educate hospital and nursing home health care professionals on processes that reduce the future occurrence of events. This project explores whether Maryland can achieve voluntary compliance with a patient safety program designed similarly to the patient safety program at the Veterans Administration (VA). The Patient Safety Center, as proposed, serving multiple types of health care delivery systems and practitioners could facilitate consensus among academic researchers and community health care providers. This would obviate the need for the authority present in a closed system, such as the VA, for achieving participation.

The long-term goal of this project is to improve the quality of patient care for all Marylanders. This will involve coordinating efforts among hospitals and nursing homes in the state to replicate, as closely as possible, the Veterans Administration's (VA) National Center for Patient Safety (NCPS) and the Patient Safety Reporting System (PSRS). The long-term objective of this project is to expand this model to other health care settings within Maryland. This includes fostering voluntary reporting and analyzing adverse events and near misses rather than relying on punitive actions.

The overall success of these specific aims will be evaluated largely by the measurement of improvements in the following four areas:

1. Creation of Maryland Patient Safety Center (MPSC): Organizational analysis and documentation to determine that MPSC is fully operational.
2. Education and Training: Increased number of hospitals and nursing homes in which the health care professionals have been trained in the RCA process. The goal is to achieve 95% of hospitals having their professionals trained and 60% of nursing homes having their professionals trained by the end of Year Three. Increased awareness and knowledge of and use of the RCA model is to be assessed by pre-training (pre-test) knowledge measurement and post-test of understanding and use of RCA in their work at two post-training time periods.
3. Voluntary Reporting: (a) Increased number of hospitals and nursing homes reporting to the MPSC. The goal is to achieve 95% participation by hospitals and 60% participation by nursing homes by the end of Year Three; and (b) increased volume of reported adverse events and near misses. Although there is no baseline for Year One, the goal is to increase reporting by 30% between Year One and Year Two and an additional 30% between Year Two and Year Three.
4. Grassroots Model: Organizational analysis to determine effectiveness of Advisory Board in achieving consensus through grassroots model. Questions to be addressed by the survey at the conclusion of the project include who were key players in advisory group professional associations or individual facilities, what methods were used to encourage reporting, and how successful these methods were in terms of generating increased reporting.

Long-term health care cost savings with the successful implementation of the MPSC are expected. Information from the VA and other sources has indicated that certain patient safety interventions can save costs from additional care resulting from adverse events. For example, the use of hip pads to prevent hip fractures associated with patient falls is a cost-effective practice that is currently the subject of a demonstration project by the VA.⁴⁸ Cost savings can also be achieved by reducing longer hospital stays and by lowering malpractice and liability expenses caused by adverse event.

⁴⁸ James Barron, Case Study: Veterans Health Administration. Risk Management Foundation of the Harvard Medical Institutions. 2002, (pp 140-144).

While the costs to states for programs to collect only ‘near miss’ information are not known, the costs to implement mandatory adverse event reporting systems has been reviewed by NASHP.⁴⁹ Five to seven people (full-time equivalents, or FTEs) are required for the administration and investigation of incidents. The costs for systems design and maintenance is approximately \$50,000 to \$275,000, in addition to \$200,000 to \$675,000 for data analyses and validation (in-house and contractual). Funding sources include state resources, such as licensure fees and fines, general funds, and legislative grants.

The Department of Veterans Affairs’ voluntary reporting system will span three years and cost \$8.2 million dollars to implement within the 172 medical centers.

B. Health Care System Initiatives

Systemic reform, that is, the improvement of those processes that affect the management of care (not that of an individual provider), has received much attention since the release of the second IOM report, *Crossing the Quality Chasm*. The IOM committee recommended that private and public purchasers of health care, health care institutions, clinicians, and patients should together redesign health care processes by focusing on systems that cause or contribute to the causation of errors. Specifically, the report states -“the health care environment should be safe for all patients, in all processes, all the time.”⁵⁰

Systemic improvements to encourage patient safety may pose a challenge to some facilities because of financial and staffing constraints; however, these efforts have great potential for bringing about broad-based improvements in patient safety. In particular, several State activities and health care-facility-based initiatives designed to encourage and facilitate systems reforms are described below.

1. State Activities to Promote Systems-Based Patient Safety

The Maryland health care regulatory system offers a unique opportunity to foster and encourage systems-focused patient safety initiatives. Listed below are proposed initiatives that can be used to encourage systemic reform in all health care settings.

The State Health Plan and Certificate of Need Activities

The Maryland Health Care Commission is responsible for the development of the State Health Plan for Facilities and Services (SHP). The Commission views the State Health Plan as a policy blueprint for positive change in health care delivery which provides guidance on resource allocation decisions based on considerations of the appropriate balance between availability, accessibility, cost, and quality of health care. The SHP contains methodologies, standards, and criteria that the Commission uses in making Certificate of Need (CON) decisions. The CON

⁴⁹ Jill Rosenthal, Maureen Booth, and Anne Barry. “Cost Implications of State Medical Error Reporting Programs: A Briefing Paper.” National Academy for State Health Policy. May 2001.

⁵⁰ Institute of Medicine. [Crossing the Quality Chasm](#).

program ensures that changes in services for health care facilities are appropriate and consistent with the Commission's policies.

The Certificate of Need (CON) Program is the means by which the Commission's statutory authority, under Code of Maryland, Health-General Article, §19-103 and 19-120 through §19-127, to review and approve new or expanded health care facilities and services subject to this authority under the law is carried out. Through CON review, the Commission implements the policies it develops and adopts as regulation in the State Health Plan, governing the development, supply, and allocation of health care resources throughout the state. COMAR 10.24.01, the procedural regulations that guide CON review, establishes administrative rules and procedures under which all reviews are conducted, and all decisions are brought to the Commission for its action. The Commission may approve, approve with conditions, or deny applications by health care providers to establish new facilities or services, to modify previously-approved projects, to relocate existing service capacity, to undertake capital projects over a set dollar threshold, or to close certain facilities or services. It is important to note that many proposals from health care practitioners or facilities do not require Certificate of Need review, and the Commission issues many such determinations of non-coverage. Other proposed projects may be exempted by Commission action from the requirement to obtain Certificate of Need.

Underlying all of the Commission's CON decisions is its statutory mission to shape a system of broad access to health care services of consistently high quality at a reasonable cost. Applications for Certificate of Need are evaluated according to the State Health Plan's review standards and need projections, and weighed against six general CON review criteria: (1) consistency with the State Health Plan; (2) need for the service; (3) positive impact of the proposed project on the existing health care system; (4) availability of financial and non-financial resources necessary to implement the project; (5) cost-effectiveness of the project compared to existing services; and (6) compliance with the terms of previously-awarded CONs.

Under the Commission's capacity to include requirements related to quality in the State Health Plan, general standards that encompass universal expectations for the delivery of acute care services by all hospitals in Maryland may include criteria related to patient safety. If patient safety requirements were to be included in a State Health Plan chapter, each facility requesting a Certificate of Need or a Certificate of Need exemption for a project would have to address and document compliance of its facility with those patient safety standards as part of its CON application or exemption request.

Hospital Rate Setting

The Health Services Cost Review Commission (HSCRC) was established by the General Assembly in 1971. The seven-member Commission is charged with reviewing and approving rates that hospitals can charge for their services and making financial information about Maryland hospitals available to the public. Based on a federal waiver from Medicare, the HSCRC sets rates for all payors - private insurance companies, HMOs, Medicare, and Medicaid. This system is referred to as the "all-payor" system where all payors pay for their share of hospital costs. Maryland is the only state in the nation where any resident can obtain care in any hospital, regardless of ability to pay. There is not a two-tiered system of care with charity hospitals for the

poor; every hospital's rates include a factor for social costs, including the uncompensated care it provides. The Uncompensated Care Fund is funded through a 0.75 percent assessment on all hospital rates. This money is used to compensate for charity care and bad debt at those hospitals with the highest levels of uncompensated care.

Implementing certain patient safety initiatives, such as CPOE and bar coding, are quite costly and require significant capital expenditures. The HSCRC rate setting system may be used to offset some of the initial expenses associated with these initiatives. Rate increases could help defer the costs of the initial start-up of the requested technology. The HSCRC could also consider whether a patient safety initiative would be cost neutral in the long run by creating greater efficiency and reducing costs associated with increased length of stay due to complications and increased costs for medical liability.

In the past, the HSCRC has allowed rate increases under the auspices of certain programs that have encouraged hospitals to undertake innovative activities that decrease costs and improve quality. When the HSCRC has handled these initiatives previously, any initial start-up or seed funding was paid back or the hospital had demonstrated the cost effectiveness of the program upon application to the HSCRC. The following example illustrates a program in which the rate-setting system encouraged hospitals to undertake certain activities that helped to address a significant problem with a costly solution, which would have been difficult, if not impossible, to solve without the HSCRC's involvement. A similar model could be used to help implement proven but costly safety initiatives.

The Nurse Support Program: In 1986, in response to a nursing shortage, the HSCRC initiated nurse education support funding through the collaborative efforts of hospitals, nursing representatives, and payors. Thirty-seven hospitals have participated in the project since its inception, and more than \$7 million in funding has been allocated. The program focused on scholarship support and hospital-based educational programs for registered nurses. In 1993, the HSCRC enhanced the program to include tuition funds for the Maryland Hospital Association's Project LINC, which focused on training minorities in health professions.

In spring 2001, the HSCRC began a new Nurse Support Program (NSP). The NSP funds recruitment and training programs for nurses and encourages innovative efforts to address the spectrum of workplace issues. Participants who receive funding from the program must commit to serving in Maryland hospitals for two years. The HSCRC views the NSP as part of an important long-term solution to the latest nursing shortage.

The program is capped at 0.1 percent of total patient revenue for the state – currently about \$6 million per year. Hospitals apply for support through a request-for-proposal process, which, in effect, permits funds to flow through the hospital as a rate increase. But, unlike a traditional rate increase, these funds are not included in the target charge-per-case calculation.

Hospital and Nursing Facility Performance Reporting

In 1999, legislation was passed (Chapter 657 of 1999-House Bill 705) that required the MHCC to develop and implement a system to compare the quality and performance of Maryland hospitals. A web-based *Hospital Performance Evaluation Guide* was released in January 2002, featuring descriptive information on the 47 Maryland acute care hospitals (<http://www.mhcc.state.md.us/hospitalguide>). Using the Guide, consumers have access to hospital-specific information, such as hospital location and contact information, the number and types of beds available at each facility, JCAHO (Joint Commission on Accreditation of Healthcare Organizations) accreditation status, and other such information. This report is useful to consumers who have the ability to plan to receive medical care. Also, it is anticipated that a well-designed performance evaluation system could promote improvements in quality of care.

In addition, the Guide features information on 33 high volume conditions (DRGs - diagnosis related groups) using data provided by the Health Services Cost Review Commission. The Guide provides hospital specific rates on volume and risk-adjusted length-of-stay for each DRG. Also featured are the hospital's risk-adjusted readmission rates for each DRG. Data are not reported if the hospital's volume for the DRG is less than 20, felt to be a threshold for valid information.

Beginning in early 2003, the Hospital Guide will include performance measures, or core measure sets, similar to that of JCAHO's ORYX initiative. The two core measure sets related to processes of care for congestive heart failure and community acquired pneumonia will be published for all Maryland acute care hospitals which meet a minimal threshold number of cases or discharges. Consumers will be able to discern a hospital's performance in each measure based on established rating criteria.

In the future, information and relevant patient safety data could be presented in the Guide to further assist consumers in their selection or evaluation of a hospital. For example, for hospitals, the use of computerized physician order entry and the use intensivists in ICUs could be reported in the Guide. In addition, those hospitals that participate in the proposed Maryland Patient Safety Center could be featured (see Patient Safety Center section above). This would give recognition to hospitals that have invested in patient safety.

The MHCC released its first state-sponsored *Nursing Home Performance Evaluation Guide* in August 2001, featuring a detailed look at over 200 comprehensive care nursing facilities and continuing care retirement communities. Available at <http://www.mhcc.state.md.us/nhguide>, the Guide enables consumers to review information on facility and resident characteristics, Quality Indicators, and any deficiencies observed during the state inspection of the nursing home. In addition, the Nursing Home Guide provides general information on patient rights, how to pay for nursing home care, and what to look for when visiting a nursing home. The purpose of the Nursing Home Guide is to improve the quality of care provided by nursing homes by establishing a common set of performance indicators and disseminating the findings of the comparative evaluation to nursing homes, consumers, and other interested parties. The presence or absence of certain patient safety-related protocols and technologies, similar to that proposed for hospitals,

could be indicated as they become more commonplace. In a similar fashion to hospital reporting, nursing homes that participate in the proposed Maryland Patient Safety Center could be featured.

2. Technological/Process Innovations

A number of technological approaches to improving patient safety have been proposed and implemented in various settings. These technologies are generally based on improving information systems and enhancing the flow of knowledge between key players providing different facets of patient care. The 1999 IOM Report gives emphasis to the role that information technologies have in patient safety improvement. JCAHO has stated “medical error reduction is fundamentally an information problem.”⁵¹ “Technology has the potential to reduce medication errors by reducing complexity, avoiding over-reliance on memory, simplifying key processes, and, if designed and implemented properly, increasing efficiency.”⁵²

The underlying basis of utilizing technology to improve patient safety is rooted in the need for an electronic medical record system (EMRS). Such a system has a number of components that should all be implemented in an integrated fashion, but, due to financial constraints, could occur over time. The components of an EMRS include the electronic medical record itself, computerized physician order entry (CPOE), a medication administration record (MAR), as well as computerized clinical decision support systems and bar code technologies for both medication administration and patient identification.

The use of manual, paper-based patient records can restrict the flow of information distribution and hamper communication between departments who are all involved simultaneously in a patient’s care. It must be made clear, however, that the implementation of technology must be accompanied with improvements to clinical processes. Technological innovation can be a neutral tool; however, the processes to which technology is applied should be efficient in and of themselves. According to the Healthcare Information and Management Systems Society, “If technology is applied to an inefficient manual process, it will retain its inefficiencies when automated.”⁵³

The following sections will focus on the CPOE component of an EMRS. Each of the other components has its benefits but their integration into a system has the largest overall impact. To date, capital expenditures by hospitals to implement these technologies have not necessitated CON approvals by the MHCC. This is either because they are under the \$1.5 million capital review threshold or, more likely, because hospitals have taken what is referred to as the “pledge,” agreeing not to have more than \$1.5 million added to their hospital rates over the debt service of the project to cover the capital costs.⁵⁴

⁵¹ Kathleen C. Kimmel, RN, MHA, CHE and Joyce Sensmeier, MS, RN, BC, CPHIMS, “A Technological Approach to Enhancing Patient Safety,” Healthcare Information and Management Systems Society, 2002, p 5.

⁵² “Medication Safety Issue Brief: Using Automation to Reduce Errors,” Joint project of the American Hospital Association, the American Society of Health-System Pharmacists and Hospitals & Health Networks.

⁵³ Kimmel and Sensmeier. “A Technological Approach,” Healthcare Information and Management Systems Society, 2002, p 1.

⁵⁴ Health-General Article, Section 19-123(k)(5)(viii).

Computerized Physician Order Entry and Clinical Decision Support

Computerized physician order entry (or CPOE) has become increasingly popular in recent years as a proposed tool to reduce the occurrence of medication errors. As defined by the Leapfrog Group, CPOE “is a clinical software application designed specifically for use by physicians to write patient orders electronically rather than on paper.”⁵⁵ Orders for medications are entered into the CPOE system instead of the physician manually writing them on paper to be transcribed by one or more intermediaries until the order arrives at the dispensing agent and then back to the patient. Many reports indicate that medication errors constitute the largest source of adverse events, and the largest number of medication errors occurs during the process of ordering or prescribing medications.⁵⁶ As such, CPOE is primarily being considered to reduce medication errors but does have other potential applications such as ordering laboratory and other diagnostic tests. Its role in reducing medication error will be the primary focus of this section. CPOE and the related requirement for integrated electronic clinical decision support can assist in reducing adverse events caused by insufficient patient information, illegible handwriting, drug-to-drug interactions, insufficiently communicated patient allergies, as well as inadequate information about the medication itself, especially given the continuous proliferation of new drugs.⁵⁷

According to a report written by Protocare Sciences under contract to the American Hospital Association, CPOE may be “used in conjunction with a pharmacy software program designed to detect potential contraindications, dosing errors or inappropriate routes of administration.”⁵⁸ As part of a facility’s information system, CPOE is a computer application that enables a physician to electronically enter medication and other treatment orders. Clinical decision support is critical to the optimal utility of a CPOE system; that is, if properly equipped with clinical decision support information, CPOE can enhance compliance with standardized practices, such as clinical practice guidelines or pathways. When optimized, various information entered into the system can be compared with other patient-specific data (i.e., patient’s history, diagnoses, allergies) and data related to the medication (i.e., drug-to-drug interaction checks; dosage recommendations). Conflicts and contraindications identified in the entered data can be conveyed to the physician or other providers as alerts, preventing potential adverse events. CPOE can enable a health care provider to individualize a patient’s treatment, essentially creating a patient-specific protocol that uses evidence-based practices to “standardize clinical decision making.” According to a study supported in part by the AHRQ, “simple computerized algorithms that generate reminders, alerts, and other information and protocols that incorporate more complex rules reduce the clinical decision error rate.”⁵⁹ However, it is critical that an excessive number of reminders and

⁵⁵ Jane Metzger and Fran Turisco, “Computerized Physician Order Entry: A Look at the Vendor Marketplace and Getting Started,” Report by the First Consulting Group for the Leapfrog Group, December 2001. <http://www.leapfroggroup.org/CPOE/CPOE%20Guide.pdf>

⁵⁶ California HealthCare Foundation, First Consulting Group, “A Primer on Physician Order Entry” Sept. 2000.

⁵⁷ Lisa K. Miller, BSH Admin., RN; Marsha S. Nelson, MBA, RN; and Bruce W. Sputlock, MD, “A Compendium of Suggested Practices for Preventing and Reducing Medication Errors,” The California Institute for Health Systems Performance. November 2001.

⁵⁸ Dorothy L. George, PharmD; Matthew F. Emons, MD, MBA; Kathryn M. Uchida, PharmD; and Jacqueline Kosecoff, PhD, “The Challenge of Assessing Patient Safety in America’s Hospitals.” Protocare Sciences, January 15, 2002. p. 1A.

⁵⁹ Alan H. Morris, MD, “Decision support and safety of clinical environments,” Quality and Safety in Health Care 11, pp. 69-75, 2002.

alerts are not generated as they may be ignored as being too much “noise” and be seen as adding intolerable time burdens to delivering care.⁶⁰

A number of external sources have been applying pressure on hospitals to adopt medication-error reducing technologies. The Leapfrog Group, a leading proponent of CPOE, has encouraged participating health care organizations to implement such systems to help reduce the occurrence of medication errors.⁶¹ The Leapfrog standard “requires that physicians enter orders electronically and that the system be able to intercept at least 50 percent of common serious prescribing errors.”⁶² In New York, a coalition of large businesses has agreed to award bonuses to providers that have instituted CPOE systems. The bonuses, in effect, act as subsidies to the implementation of the system; however, the cost of implementing the system is assumed by the health care facility.⁶³ California enacted a law in 2000 that requires, as a condition of licensure, every general acute care hospital, special hospital, and surgical clinic to adopt a formal plan to eliminate or substantially reduce medication-related errors. With the exception of small and rural hospitals, this plan must include technology implementation, such as, but not limited to, CPOE or other technology that, based upon independent, expert scientific advice and data, has been shown effective in eliminating or substantially reducing medication-related errors.⁶⁴

The cost associated with the implementation and maintenance of a CPOE system is relatively high and therefore unattainable in the short-term by many health care facilities. At Brigham and Women’s Hospital (BWH) in Boston, MA, it is estimated that the development and implementation of its CPOE system cost \$1.9 million. In addition, \$500,000 is spent annually on maintenance. Leapfrog researchers estimated that the implementation costs for a CPOE system could range from approximately \$496,000 to almost \$15 million depending upon the degree of sophistication of the hospital’s computer information system (CIS).⁶⁵ Another estimate projects the implementation costs in a 200-bed hospital could range from approximately \$1.2 to \$7.4 million over a 5-year period.⁶⁶ In New York, hospital executives speculate that implementing CPOE systems could cost from \$5 million to \$60 million depending on the size of the hospital and degree of CIS sophistication.⁶⁷

However, regardless of the upfront costs of implementing a CPOE system, the advantages of such a system are considerable – a reduction in the occurrence of adverse events; a reduction in utilization and length-of-stay; improvement in the coordination of care; and a reduction in the variation of care. It can also assist providers in coping with the exponential increase in medical knowledge that is appearing in the medical literature. In addition, with increased emphasis on disease management, CPOE and a computerized medical record can allow the capture of a

⁶⁰ Kaveh G. Shojania, Clinician-Researcher, University of California, San Francisco, “Important Practical Limitations for Decision Support,” Letter to the Editor, British Medical Journal, August 5, 2002.

⁶¹ Dagmara Sarudi, “The Leapfrog Effect,” Hospital and Health Networks, May 2001.

⁶² Peter Kilbridge; Emily Welebob, and David Classen, “Overview of the Leapfrog Group Evaluation Tool for Computerized Physician Order Entry,” Report by the First Consulting Group for the Leapfrog Group. December 2001.

⁶³ Milt Freudenheim, “Companies Start Fund to Reward Hospitals for Better Care,” The New York Times, October 18, 2001

⁶⁴ http://www.leginfo.ca.gov/pub/99-00/bill/sen/sb_1851-1900/sb_1875_bill_20000928_chaptered.pdf

⁶⁵ John D. Birkmeyer, M.D., et al., Economic Implications of the Leapfrog Safety Standards, June 2001.

⁶⁶ Dagmara Scalise, “CPOE, An Executive’s Guide,” Hospital and Health Networks, 76(6), June 2002.

⁶⁷ Freudenheim, “Companies Start Fund to Reward Hospitals for Better Care.”

patient's aggregate information to support a system of care management.⁶⁸ These improvements in patient safety and quality of care have a positive, long-term impact on reducing costs. However, while many organizations are very interested in this type of system, the initial expense of purchasing and implementing such a system is often fiscally prohibitive. To cope with the high costs of these systems, some facilities have sought to spread the costs over time by implementing CPOE in stages. In addition, a hospital's computer information system that is already CPOE-enabled will, in turn, cost the hospital less compared to a system that requires replacement.

While studies of aggregate costs saved by the implementation of CPOE systems are somewhat limited, several show substantial savings. A 2001 study by the Agency for Healthcare Research and Quality (AHRQ) concluded that computerized systems can prevent somewhere between 28 to 95 percent of ADEs (adverse drug events) by reducing medication errors which, in turn, could save each hospital as much as \$500,000 annually in direct costs.⁶⁹ According to a study of the BWH CPOE system, the financial benefits extended beyond medication-related events with net savings to the BWH system of an estimated \$5-10 million per year.⁷⁰ Another study, using a randomized controlled trial, found that use of computerized physician order entry as compared to paper ordering resulted in 12.7% lower charges and 13.1% lower costs.⁷¹

Bar Coding

Bar coding has been utilized in many industries for a number of years. The most common usage is the UPC symbols attached to most retail goods and read by a scanner at the checkout line. Bar coding in health care could work in the same general fashion and some health care industries are just beginning to take advantage of this technology. Bar coding has been pervasive in health care materials management but has not been widespread in the clinical setting. Bar coding is now being promoted and encouraged to serve two purposes which both lead to improvements in patient safety. Bar coding is being utilized primarily to decrease errors related to patient misidentification and to reduce medication administration errors. Bar coding also aids in laboratory specimen handling and in medical record keeping.

Patient Identification: Bar-coded patient identification is envisioned as replacing the current text-filled wristbands. In addition to ensuring that the correct patient is getting the correct treatment or surgery, bar-coding could track any medications or blood products to be given and any specimens taken from the patient.

The new JCAHO patient safety goals that have been approved for implementation, effective January 1, 2003, include the goal of improving the accuracy of patient identification. The recommendations associated with the goal do not necessarily call for the use of bar code technologies to achieve it. The recommendations are: (1) use at least two patient identifiers

⁶⁸ AHA Guide to Computerized Physician Order-Entry Systems, AHA, November 2000.

⁶⁹ *Reducing and Preventing Adverse Drug Events Decreases Hospital Costs*. Press Release, April 11, 2001. Agency for Healthcare Research and Quality, Rockville, MD. www.ahrq.gov/news/press/pr2001/adepr.htm

⁷⁰ JM Teich, JP Glaser, RF Beckley, M Aranow, DW Bates, GJ Kuperman, et al. "Toward Cost-effective, Quality Care; the Brigham Integrated Computing System" Proc 2nd Nicholas E. Davies CPR Recognition Symposium. Washington DC: Computerized Patient Record Institute. 1996; pp. 3-34.

⁷¹ W.M. Tierney, M.E. Miller, J.M. Overhage, and CJ McDonald, "Physician Inpatient Order Writing on Microcomputer Workstations. Effects on Resource Utilization," JAMA, 269(1993): 379-383.

(neither to be the patient's room) whenever taking blood samples or administering medications or blood products; and (2) prior to the start of any surgical or invasive procedure, conduct a final verification process, such as a "time out," to confirm the correct patient, procedure, and site, using active – not passive – communication techniques.

Bar coding to improve patient identification is now being increasingly used to enhance safety. Methods of identification less expensive than bar coding could also improve patient safety. Such verification methods include asking the patient for name and/or birth date and photo identification that could be taken during the admission process. For patients with behavioral disorders, dementia, coma and abnormal mental status, other methods would be required such as asking an attending staff member to verbally confirm identification. Wristbands with information that the patient can confirm may also be effective. A specific admissions protocol to "label" the patient accurately should be the first step in any safety-enhancing patient identification process (i.e., a computer-generated label with unique patient information that the person putting it on the patient confirms with the patient and signs or initials as a confirmation of the check).

Medication Errors: According to the 1999 IOM Report, improper doses, inaccurate records, and mix-ups of drugs or patients are common causes of medication errors. Bar coding technology can reduce errors related to the dispensing and administration of medication. The adoption of bar coding technologies has been promoted by a number of organizations in their recommendations for improving patient safety. These organizations, in addition to the IOM, include the American Society of Health-System Pharmacists, the National Patient Safety Partnership, the Massachusetts Coalition for the Prevention of Medical Errors, and the National Coordinating Council for Medication Error Reporting and Prevention.

Several case studies of bar code implementation show substantial success in reducing medication errors. Concord Hospital in New Hampshire cites an 80 percent decrease in medication administration errors.⁷² The Department of Veteran Affairs (VA) developed a system called Bar Code Medication Administration (BCMA), with a prototype that was tested at the Eastern Kansas Health Care System. The system validates medications for inpatients and accurately documents the administration process. The pilot project was so successful that the VA has implemented the software in all of its medical centers nationwide. In one VA hospital, there was a decrease of over 86 percent in the reported error rate in the dispensing of medications between 1993 (the last year of the manual system) and 2001. During that same period, improvements between 62 percent and 93 percent were experienced when measuring different types of medication errors: wrong medication given; incorrect dose; wrong patient; wrong time; and medications not given.⁷³

Bar coding at the clinical level has not been as widespread as one would expect. The adoption of this technology has been thwarted by the misaligned incentives in the market. Most providers and facilities want to have the bar coding of medications done at the unit-of-use level, meaning the dosage of the medication that would be administered at the point of care has the bar

⁷² D. DePiero, Personal Communication with DW Bates cited in "Using Information Technology to Reduce Rates of Medication Errors in Hospitals" *British Medical Journal*, March 2000.

⁷³ Connie Johnson, Russell Carlson, Chris Tucker, Candice Willette, "Using BCMA Software to Improve Patient Safety in Veterans Administration Medical Centers," *Journal of Healthcare Information Management*, 16(1), Winter 2000.

code on it. It is quite costly for manufacturers to bar code at this micro-level. The manufacturer does not reap economic benefit for doing so and, in fact, the manufacturers are moving away from even packaging drugs at the unit-of-use scale at all. The technology exists to provide unit-of-use bar coding but a manufacturer would have to invest in substantial start-up costs for the graphics, printing, and quality control. Conversely, facilities have not invested in scanning technologies because they are currently expensive and there are very few bar coded medications to read. Finally, the commercial software developers have not developed the systems because the facilities have not been demanding them.⁷⁴

A number of organizations have called for the federal government via the Food and Drug Administration (FDA) to mandate bar codes at the unit-of-use level. The FDA held a public hearing on July 26, 2002 to solicit comments for the development of regulations on bar code labeling. The meeting was held under the auspices of supporting the initiative of the Secretary of HHS to reduce medication errors. At the hearing, hospital groups and patient safety advocates called for the FDA to expedite its efforts to require bar coding. The drug manufacturers expressed concern about how quickly they could implement it and were also reluctant to move back toward unit-dose packaging which is more costly to produce.

Intensivists

Intensivists (physicians who specialize in critical care medicine) are trained to care for the sickest patients, those cared for in hospital intensive care units (ICUs). It is estimated that approximately one-third of ICU patients are cared for by an intensivist.⁷⁵ Approximately 10 percent of hospital beds are found in the ICU. The mortality rates of ICU patients range from 12 to 17 percent with approximately 500,000 patients dying in ICUs annually in the United States.⁷⁶

The use of intensivists to manage the care of patients in ICUs has been shown to improve the quality of care. A recent systematic review of various observational studies to determine the relationship between ICU physician staffing and patient outcomes reported that the use of intensivists exclusively to manage patients in the ICU, or through mandatory consultations with intensivists for patients in the ICU, reduces the likelihood of hospital and ICU mortality and decreases length-of-stay.⁷⁷ Since most patients in ICUs today are cared for by physicians who are not intensivists or are managed by intensivists only when electively consulted by attending physicians, it is recommended that the ideal ICU organization or staffing ratio be studied further.⁷⁸ Another structured review of nine studies estimated that the use of intensivists could reduce mortality rates by 15 to 60 percent; using conservative estimates, the authors project that almost 54,000 lives could be saved annually by the adoption of an intensivist-model of ICU care.⁷⁹

⁷⁴ "Bar Coding for Patient Safety" Advocacy White Paper, Healthcare Information and Management System Society. 12/27/01.

⁷⁵ Peter J. Pronovost, Derek C. Angus, Todd Dorman, Karen A. Robinson, Tony T. Dremsizov, and Tammy L. Young, "Physician Staffing Patterns and Clinical Outcomes in Critically Ill Patients: A Systemic Review." *JAMA*, 288: 2151-2162. 2002.

⁷⁶ *Making Health Care Safer: A Critical Analysis of Patient Safety Practices*, AHRQ, July 20, 2001.

⁷⁷ Pronovost, et al., "Physician Staffing Patterns and Clinical Outcomes in Critically Ill Patients: A Systemic Review."

⁷⁸ *Ibid.*

⁷⁹ Michael P. Young and John D. Birkmeyer, "Potential Reduction in Mortality Rates Using an Intensivist Model to Manage Intensive Care Units," *Effective Clinical Practice*, Nov/Dec 2000, Vol 3, No. 6.

The Leapfrog Group has endorsed the use of intensivists in the ICU setting as one of its three patient safety standards. In order to qualify, hospitals must require intensivists to be certified in critical care medicine, present in the ICU during daytime hours, and provide care to the ICU patients solely.⁸⁰ According to Leapfrog, studies have shown that the use of intensivists reduces ICU deaths by over ten percent.⁸¹

Staffing ICUs with intensivists can be costly; Leapfrog researchers estimated that the cost of hiring intensivists and physician extenders in hospital ICUs ranges from almost \$400,000 to \$505,000 per hospital based upon the number of ICU beds. However, the savings incurred from reduced length-of-stay in ICUs and hospitals and improved ICU utilization can result in a savings of over \$1 million to almost \$4 million.⁸² Net savings (taking into account the costs) are projected to range from \$771,000 to over \$3.4 million. The benefits come from more appropriate ICU admissions, reduced ICU and hospital length of stay, and reduced ancillary costs.⁸³

Currently, intensivists only comprise 10% of physicians in the country. With the shortage of such physicians, it is highly unlikely that all hospital ICUs can be fully staffed to the Leapfrog standards in the foreseeable future. It should be noted that the results of the survey of Maryland health care facilities indicated that over half of the acute care hospitals currently have intensivists managing ICUs (56% of respondents). Savings could be realized at all hospitals if intensivists were more equally distributed (instead of concentrated in a select number of facilities).

3. Initiatives To Reduce Medication Errors

Other Technology-Based Initiatives Related to Medication Errors

According to studies by the IOM, adverse events related to medication errors are estimated to be responsible for the deaths of over 7,000 people in 1993 and the cost associated with preventable adverse drug events is a staggering \$2 billion annually.⁸⁴ Medication errors occur during the many stages between the physician's thought to use a drug and the drug's administration to the patient. Those stages are: writing the order or prescription; order transcription; dispensing; administration; and monitoring.

Less costly than CPOE systems, other forms of automation can assist in reducing medication errors at all stages of the process.⁸⁵ As noted above, the introduction of automated technologies is not a guarantee for improved patient safety. The technologies must be coupled with

⁸⁰ Peter Pronovost, M.D., Ph.D., Hugh Waters, Ph.D., and Todd Dorman, M.D., "Intensive Care Unit Physician Staffing," Leapfrog Patient Safety Standards – Economic Implications, John D. Birkmeyer, M.D., Research Director and Editor. June 2001.

⁸¹ John D. Birkmeyer, M.D., et al., Leapfrog Patient Safety Standards: The Potential Benefits of Universal Adoption. November 2000.

⁸² The costs and savings are estimated for ICUs with 6 beds, 12 beds, and 18 beds. Peter Pronovost, M.D., Ph.D., Hugh Waters, Ph.D., and Todd Dorman, M.D., "Intensive Care Unit Physician Staffing," Leapfrog Patient Safety Standards – Economic Implications, John D. Birkmeyer, M.D., Research Director and Editor. June 2001.

⁸³ John D. Birkmeyer, M.D., Economic Implications of the Leapfrog Safety Standards. June 2001.

⁸⁴ Institute of Medicine, To Err is Human, p. 27.

⁸⁵ DW Bates, "Using Information Technology to Reduce Rates of Medication Errors in Hospitals," British Medical Journal, 2000.

appropriate process changes to ensure that inefficient or even dangerous processes do not become even more so through the use of automation. The following are examples of technologies that can, to some degree, assist in improving patient safety:

- Pharmacy information systems: These computer systems have the ability to look at inappropriate dose ranges, drug-to-drug interactions, and potential allergies to a drug.
- Automated medication-dispensing devices: These devices operate by dispensing medications using standardized dosing requirements and can also assist in the control of dispensing drugs to the wrong patient.
- Computerized Medication Administration Records (MAR): An MAR is the record which contains information about the medications, doses and frequencies which are to be and have actually been given to a patient, as noted by the administering clinicians. Electronic MARs, especially when linked with a CPOE system, help to maintain a patient's medication record in a legible format that is available to all parties who are given access to the record. Errors which are primarily related to medication administration would be reduced by this technology.
- Robots for Filling Prescriptions: The proper dispensing of medications is another avenue by which errors can be reduced. This technology has been in use by a number of larger hospitals and, as costs decrease, has been moving into smaller facilities.
- “Smart” Infusion Pumps: These infusion pumps can be pre-programmed with certain drug protocols which do not allow inappropriate doses (i.e., those falling outside of the set parameters or recommended ranges).
- Computer Alert Systems: Computer alert systems can be designed to detect preventable adverse events before they occur. Using this system, one hospital was able to detect opportunities to reduce the occurrence of preventable medication errors at a rate of 64 out of every 1000 patient admissions.⁸⁶

Non-Technology-Based Initiatives Related to Medication Errors

As an alternative to costly technological systems requiring lengthy planning, financing, and implementation, several health care organizations have proposed a number of activities that can be instituted within a short period of time (less than a year) and have a relatively low financial burden on facilities. The majority of these initiatives have been proposed in an effort to reduce the occurrence of medication errors.

In *To Err Is Human*, the **Institute for Medicine**⁸⁷ recommended certain strategies to improve medication safety including:

⁸⁶ RA Raschke, et al., “A Computer Alert System to Prevent Injury from Adverse Drug Events.” *JAMA* 1998; 280: pp. 1317-1320.

⁸⁷ Institute of Medicine. *To Err is Human*.

- Implement standard practices for medication doses, dose timing, and dose-scales in a given patient care unit;
- Standardize prescription writing and prescribing rules;
- Limit the number of different kinds of equipment;
- Implement unit dosing;
- Have the central pharmacy supply high-risk intravenous medications;
- Use special procedures and written protocols for the use of high-risk medications;
- Do not store concentrated solutions of hazardous medications in patient care units;
- Make important patient information available at the point of patient care; and
- Improve patients' knowledge about their treatment.

As part of its continuing patient safety commitment, the **Joint Commission on Accreditation of Healthcare Organizations (JCAHO)** released this past summer its *National Patient Safety Goals*. The six goals make up the first set of goals in a series to be released each year. As part of the initial set of six goals, the *Sentinel Event Alert* Advisory Group developed 11 recommendations based on previous *Alert* recommendations (see Appendix C). These recommendations will be subject to survey beginning in January 2003. Hospitals will be cited if these recommendations (or approved alternatives) are not implemented.

Several issues of the JCAHO publication, *Sentinel Event Alert*, have focused on educating health care organizations about medication errors. For example, the May 2001 issue identified 'look-alike, sound-alike drug names' as a major type of medication error, accounting for approximately 15 percent of all reports to the USP Medication Errors Reporting program. Contributing to the problem of confusing names among the tens of thousands of brand and generic drugs currently marketed are illegible handwriting, new products, incomplete knowledge of drug names, and similar packaging or labeling. While the problem of similar drug names is being addressed by various industry and Federal agency review processes and initiatives, such as the FDA's intensive risk analysis system for evaluating proposed proprietary drug names, new names that are similar to existing ones continue to be approved and introduced in the market.

Sentinel Event Alert also offered several risk reduction strategies for 'look-alike, sound-alike drug names,' including never relying solely on one's memory of problem name pairs, providing the generic and brand names on all medication labels, and carefully selecting formularies of alternative medications without nomenclature problems. In addition, JCAHO recommended that sound-alike drugs should be identified as being at "high-risk" for potential error, and that extra steps should be taken to ensure that these products are ordered, dispensed, and administered properly.⁸⁸

According to information collected by **U.S. Pharmacopeia's (USP)** Medication Errors Reporting Program, between January 1996 and December 2000, 15 percent of all reports were caused by confusion over similar sounding drug names. While many times the drugs do not generally sound alike or look alike in print, the confusion occurs during verbal communication or when written orders are illegible. USP's March 2001 Quality Review (available at <http://www.usp.org>) provides a comparison of many sound-alike, look-alike drug names that have

⁸⁸ *Sentinel Events Alert*, Issue 19, May 2001. Available online at <http://www.jcaho.org>

caused medication errors. In addition, the Institute for Safe Medication Practices (ISMP) notes a number of practices that administrators and clinicians can use to prevent medication errors based on similar-sounding drug names including:

- Look for the possibility of name confusion when adding a new product to the formulary;
- Require that prescriptions specify the dosage form, drug strength, and complete directions;
- Accept verbal or telephone orders only when absolutely necessary; insist that each order is repeated back by staff;
- Change appearance of look-alike, sound-alike drugs on computer screens, pharmacy and nursing staff unit shelf labels and bins;
- Affix name alerts to areas where such drugs are stored; store in different locations if possible;
- Open the prescription bottle in front of the patient to confirm expected appearance and confirm the indication; and
- Encourage the reporting of adverse events and near-misses with look- and sound-alike product names so as to establish protocols for dealing with these medications.⁸⁹

In response to state legislation requiring general acute care hospitals, surgical clinics, and special hospitals to develop plans to reduce medication errors, **The California Institute for Health System Performance** issued a report in 2001 outlining both long-term, capital-intensive projects and short-term, low cost initiatives.⁹⁰ Within each section of the report (each related to a phase of providing medication) are examples of inexpensive projects, many of which can be implemented immediately and with minimal effort, including:

- Pre-printed standardized orders;
- Education/dissemination of drug knowledge (such as pocket guides for high-risk drugs, clinical pharmacy rounding, and safety alerts);
- Improving written orders by eliminating the use of apothecary symbols, requiring unclear orders to be referred back to the author for clarification, and publicizing error examples after removing patient and provider identifying information;
- Strategies to prevent dosage calculation errors; and
- Strategies to improve verbal orders.

The **California Medical Association** (CMA) in conjunction with several liability insurers developed principles to promote the safe use of medications.⁹¹ These principles focus on the relationship between a knowledgeable physician and an informed patient. These principles include:

- Write the condition for which the drug is being prescribed directly on the prescription;
- Ask patients about allergies to medications, foods, and other substances and document them on the patient record;
- Print all prescriptions to assure legibility;

⁸⁹ ISMP Medication Safety Alert. "What's in a Name? Ways to Prevent Dispensing Errors Linked to Name Confusion." June 12, 2002. www.ismp.org/MSAarticles/NamePrint.htm

⁹⁰ Lisa K. Miller, et al., "A Compendium of Suggested Practices for Preventing and Reducing Medication Errors."

⁹¹ California Medical Association, <http://www.cmanet.org>.

- Spell out abbreviations for the directions of how to take the drug (i.e., “four times daily” instead of “q.i.d.”);
- Insert a leading zero (0) before any decimal point of a fractional number;
- Write out numbers; and
- Use a dedicated medication control record that can be attached to each patient’s chart.

The **Massachusetts Coalition for the Prevention of Medical Errors and the Massachusetts Hospital Association** have formulated and are promoting a number of best practice recommendations for medication administration processes and procedures that can be undertaken in the short-term:

- Maintain unit-dose distribution systems (either manufacturer prepared or repackaged by pharmacy) for all non-emergency medications;
- Institute pharmacy-based IV admixture systems to simplify the medication administration process on the patient care floors and reduce the chances of calculation and mixing errors;
- Remove concentrated potassium chloride (KCl) vials from nursing units and patient care areas; stock only diluted premixed IV solutions on units;
- Develop special procedures for high-risk drugs using approaches which include written guidelines, checklists, pre-printed orders, double-checks, special packaging, special labeling, and education;
- Make readily accessible to clinicians information on new drugs, infrequently used drugs, and non-formulary drugs so it can be used at the site of ordering, dispensing, and administering medications (e.g., have pharmacist round with doctors and nurses; distribute objective information via newsletters, drug summary sheets, and computer aids; and provide access to the Physician Desk Reference, formularies, and other resources);
- Provide physicians, nurses, pharmacists, and all other clinicians involved in the medication administration process with orientation and periodic education on ordering, dispensing, administering, and monitoring medications;
- Educate patients in the hospital, at discharge, and in ambulatory settings about the safe and accurate use of their medications; and
- Have a pharmacist available on-call after hours of pharmacy operation.

In an attempt to maximize patient safety, the **Pharmacy Society of Wisconsin (PSW)** has identified minimum practice standards and best-demonstrated practices for each phase of the medication use process in its *PSW Medication Use Practice Standards to Maximize Patient Safety* (2001).⁹² The six phases include: (1) Prescribing/Medication Determination; (2) Medication Preparation, Dispensing and Counseling; (3) Medication Administration; (4) Monitoring/Assessment of Patient; (5) Purchasing/Inventory Management; and (6) Systems of Care. The standards, which allow practitioners to take a proactive approach to medication safety in any practice setting, represent the first phase of a project that will also develop tools to assist health care providers in the implementation of the standards. PSW identifies minimum practice standards as the standard of care in all applicable practice settings. For example, in the Prescribing/Medication Determination phase, minimum standards include:

⁹² <http://www.pswi.org/professional/standards/intro.htm>

- Do not use abbreviations for medications;
- Provide weight and date of birth with all pediatric prescriptions; and
- Write all prescriptions using the metric system.

Best demonstrated practices are defined as those that are optimal and may be completely implemented in many organizations, but which may require significant resources for their effective implementation. Examples in the Prescribing/Medication Determination phase include:

- Avoid all abbreviations;
- Provide patient allergies, weight, and date of birth for all prescription orders; and
- For pediatric patients, include the calculated dose and the mg/kg dose on the prescription.

The **Florida Hospital Association** (FHA) has also developed an extensive list of safe medication practices.⁹³ The model practices were developed so that all hospitals could implement them regardless of their size, level of automation, and location. The FHA notes that they do not constitute a standard of care.

4. Other Types of Systemic Improvement

Culture of Safety

For any change to take place, the IOM concludes that health care leaders must encourage a culture of patient safety. In order to implement any improvement in the care process, support from management and staff is critical. The key to creating and maintaining a supportive culture that embraces patient safety initiatives is the organization's leadership. The success of any patient safety program or plan is only as effective as that of the health care facility's management. The IOM identified a number of principles by which leadership can promote a culture of safety. These principles include:

- "Make patient safety a priority corporate objective;
- Make patient safety everyone's responsibility;
- Make clear assignments for and expectations of safety oversight;
- Provide human and financial resources for error analysis and systems redesign; and
- Develop effective mechanisms for identifying and dealing with unsafe practitioners."⁹⁴

Several principles that guide the success of health care leaders are listed in The California Institute for Health Systems Performance *A Compendium of Suggested Practices for Preventing and Reducing Medication Errors*.⁹⁵ Examples include:

- An organization's strategic goal and core value is patient safety;
- Staff is empowered. "Patient safety is everyone's responsibility;"
- Patient safety objectives and expectations are clearly defined; and

⁹³ Florida Hospital Association. www.fha.org/pttoolkit.html.

⁹⁴ Institute of Medicine, *To Err is Human*, p.166.

⁹⁵ Lisa K. Miller, et al., "A Compendium of Suggested Practices for Preventing and Reducing Medication Errors."

- Senior leadership and the governing body monitor patient safety (activities, rate of adverse events).

Executive “walkrounds” have also been promoted as demonstrating tangible evidence of a culture of safety. Facility executives and the patient safety officer visit patient care units and elicit information that is specifically focused on safety: systems that fail; systems that do not support individuals; and adverse events and near misses. Promoted extensively by Dr. Allan Frankel at the Partners Health Care System in Boston, MA, these “walkrounds” show the facility’s leaders publicly and actively supporting safety efforts through the frank discussions with practitioners and staff. They encourage an open discussion of adverse events and, if followed through with systemic changes based on what is learned during the walkrounds, can show the frontline workers that there is a real commitment to patient safety on the part of a facility’s leadership. A formal method of feedback to the frontline staff is essential to move the organization toward adopting a culture of safety.

The concern about legal protections from malpractice litigation and discovery of evidence has limited health care leadership and staff from fully implementing patient safety initiatives in many facilities. As noted by the IOM, the protection of reported data pertaining to adverse medical events is crucial to encourage reporting of adverse events and near misses. They recommend that any reporting done through a mandatory reporting system (which would be for specifically-defined “serious” events) should be subject to disclosure to maintain a certain level of accountability in the system. Information reported in a voluntary system (for “near misses” and less injurious adverse events) requires protections for that system to work. In Maryland, the proceedings, records, and files of a medical and dental review committee are protected under confidentiality and peer review protections unless either a civil action is brought by a party to the review committee proceedings who claims to be aggrieved by the decision of the review committee or the information considered by the review committee would be subject to discovery and introduction into evidence in a civil trial.⁹⁶

In order to develop a culture of safety, a culture of openness must be created including the voluntary disclosure of adverse events, the acknowledgment of responsibility, and apology for adverse events. This acknowledgment must be accompanied with a move beyond placing blame to one that facilitates solutions so as to create a culture of shared responsibility while recognizing individual accountability.⁹⁷

Clinical Pharmacists on Patient Care Teams

Pharmacists’ involvement in patient safety activities related to medication errors in the clinical setting is currently done to some extent as many pharmacists in the hospital setting offer consultation services for patients. A study examining the relationship between the use of pharmacists in clinical rounds in intensive care units and the rate of medication errors found that

⁹⁶ Health Occupations Article, Sections 4-501 and 1-401.

⁹⁷ Alden Solovy, “At Leadership Forum, Hospital Execs Brainstorm Approaches to Patient Safety,” Hospitals & Health Networks, April 2001.

by involving pharmacists in medication orders, the occurrence of medication errors was reduced.⁹⁸ The results of the study indicated that the use of pharmacists in a patient care team significantly reduced the rate of adverse drug events by 66%.⁹⁹ Pharmacist services in the outpatient setting (for example, ambulatory care centers) may positively impact patients with certain chronic conditions; however, based on the limitations of the studies, it was recommended that additional research be conducted.¹⁰⁰

Based on research, the estimated cost savings associated with including pharmacists in the patient care team for hospital rounds ranged from \$270,000 to almost \$400,000. In the outpatient setting, savings may be incurred through a decrease in specialty visits and medication costs, and an increase in scheduled service utilization.¹⁰¹

Human Factor Engineering

Human factor engineering to improve patient safety is based on the reality that human beings are not infallible. The study of human factors involves looking at the way in which human beings interact with their work. Studies of human performance and error have been undertaken in many high-risk industries including the aviation and nuclear power industries. Health care is an area of high risk and high complexity, performance expectations are extremely high, and errors and their outcomes can be more subtle than airline or nuclear power plant accidents.

Error is inevitable because of human limitations, including: limited memory capacity, limited mental processing capacity, the adverse aspects of stress, the negative influence of fatigue and other physiological factors, along with other cultural effects (i.e., how juniors relate to their seniors; how information is shared; adherence [or lack thereof] to rules) and the possibility of flawed teamwork.¹⁰² It is critical to understand that the vast majority of medical errors are not intentional and that “good” people can produce bad outcomes. Without this realization, patient safety improvement will continue to focus on the individual who commits an error and will make insufficient allowance for limitations in human performance.¹⁰³

Human factors must be taken into consideration when designing processes within the care systems. Organizational factors that influence the behavior of operational personnel play a critical role in success or failure in a complex work setting.¹⁰⁴ In addition, human factor engineering can be applied to the technologies that are introduced into the complex medical system. Studies have

⁹⁸ Lucian L. Leape, David J. Cullen, Margaret Dempsey Clapp, Elisabeth Burdick, Harold J. Demonaco, Jeanette Ives Erickson, and David W. Bates, “Pharmacist Participation on Physician Rounds and Adverse Drug Events in the Intensive Care Unit,” *JAMA*, 282(3), July 21, 1999.

⁹⁹ *Ibid.*

¹⁰⁰ Kaveh G. Shojania, Bradford W. Duncan, Kathryn M. McDonald, Robert M. Wachter eds. *Making Health Care Safer: A Critical Analysis of Patient Safety Practices. Evidence Report/Technology Assessment No. 43* (Prepared by the University of California at San Francisco-Stanford Evidence-based Practice Center under Contract No 290-97-0013), AHRQ Publication No. 01-E058, Rockville, MD: Agency for Healthcare Research and Quality. July 2001.

¹⁰¹ *Ibid.*

¹⁰² Robert L. Heimrich, PhD, Professor Psychology at the University of Texas at Austin. Presentation to the National Patient Safety Foundation conference “Patient Safety: Let’s Get Practical”, Indianapolis, IN, April 22-24, 2002.

¹⁰³ Testimony by Deborah Huber, RN on February 11, 2002 to Nevada’s Legislative Committee on Health Care’s Subcommittee. Published in HealthInsight’s *QualityInsight*, Summer 2002.

¹⁰⁴ Lucien Leape et al, “Promoting Patient Safety by Preventing Medical Error,” *JAMA*, 280(16), Oct 28, 1998.

shown that increasingly complex medical devices, while engineered to reduce errors, can actually contribute to errors because of the breakdown at the human-computer interface.¹⁰⁵ Medical devices that require a complicated sequence of commands or that possess multiple modes and cryptic displays can force clinicians to work around those difficulties thus increasing the possibility of additional adverse events. Human factor engineering can be utilized to guard against technologies that end up being designed without recognition of human limitations.

Failure Mode and Effects Analysis

Failure Mode and Effects Analysis (FMEA) is based on an engineering technique that requires the user to focus on the processes of an event or function and designate a risk priority number to designate the likelihood of the event occurring. Instead of analyzing an event after it has occurred (such as performing a root cause analysis on an adverse event), FMEA is a proactive process used to analyze processes or areas that may be vulnerable to error. An example is reducing the risk of confusion between, and possible adverse drug event caused by, two drugs with similar names. The JCAHO recently began requiring hospitals to conduct proactive risk management activities, including FMEA, on one high-risk process annually.¹⁰⁶

The National Center for Patient Safety of the Department of Veterans Affairs, in consultation with Tenet Health System, developed a similar tool for use in health care settings. Known as HFMEA, or Health Care Failure Mode and Effect Analysis™, this process is used by a multidisciplinary team to proactively analyze a process that is considered highly vulnerable or of high risk. Several steps guide the team through the process: define the topic; assemble the team; describe the process in detail; conduct a hazard analysis; determine actions for each identified “failure” in order to eliminate the failure; and identify outcome measures to ensure process changes. In addition, an individual must ensure that the action has been completed.¹⁰⁷

5. Related Issues

Evidence-Based Patient Safety Practices

The Agency for Healthcare Research and Quality (AHRQ) published *Making Health Care Safer: A Critical Analysis of Patient Safety Practices*¹⁰⁸ following the 1999 release of the Institute of Medicine’s medical errors report. AHRQ commissioned the University of California at San Francisco (UCSF) and Stanford University’s Evidence-Based Practice Center (EPC) to review the scientific literature about safety improvement. The charge to the EPC was three-fold: (1) review the existing evidence on practices relevant to improving patient safety; (2) present those findings to the Safe Practices Committee of the National Quality Forum (NQF); and (3) grade the practices on the strength of the evidence and the need for further research. The publication

¹⁰⁵ David Woods, Studies in Human Factors as cited in an untitled document from Ohio State University at <http://www.osu.edu/units/research/archive/techmed.htm>

¹⁰⁶ Joint Commission Resources. Patient Safety Standards-Hospitals, <http://www.jcrinc.com/subscribers/printview.asp?durki+2973>

¹⁰⁷ Josephy DeRosier, Erik Stalhandske, James P. Bagian, Tina Nudell. “Using Health Care Failure Mode and Effect Analysis™: The VA National Center for Patient Safety’s Prospective Risk Analysis System,” The Joint Commission Journal on Quality Improvement, May 2002.

¹⁰⁸ Kaveh G. Shojania, et al., Making Health Care Safer: A Critical Analysis of Patient Safety Practices.

includes 79 specific practices that contribute to safer patient care and validates each one according to current research. Out of 79 practices, 11 practices were deemed to have strong evidence for having a salutary effect when implemented (see Appendix I for the practices). These 11 practices received the authors' support for more widespread implementation.

Several procedures long advocated by safety experts were omitted from the list, such as computerized physician order entry systems to decrease medication errors and changes in nursing staffing patterns to decrease mortality, because of the lack of patient safety research that quantifies the cost, complexity, and current utilization of these practices. While acknowledging the importance of the compendium of evidence-based practices, several patient safety authorities have noted the limitations of the study.¹⁰⁹ They differentiate between adverse events that are caused by preventable medical errors and those that are caused by an error in treatment. While preventing both types of adverse events would improve the quality of care, most system-based patient safety initiatives focus on those events caused by preventable medical errors. The evidence report, however, is primarily weighted toward those outcomes that could be improved by the adoption of certain standards of medical care. This bias is a result of the fact that the AHRQ study's authors admit that they looked to where the evidence-based studies led them; as such, most research has been in the area of treatment advances.

Leape et al note that several key patient safety practices were not considered in the AHRQ report because of "inadequate evidence, either because of lack of data from controlled trials, or because the available data did not prove a reduction in AEs (adverse events)."¹¹⁰ Controlled experiments with randomized patient populations are difficult and expensive to conduct for many systems-based initiatives. They concluded that the "prudent alternative is to make reasonable judgments based on the best available evidence combined with successful experiences in health care."¹¹¹

Referrals Based on Volume-Outcome Relationship

The Leapfrog Group encourages its members to refer patients to those hospitals that perform a high volume of procedures for selected treatments. This standard was chosen based on evidence that hospitals treating a significant number of patients (high volume) with certain high-risk conditions experience lower mortality rates. For certain elective procedures, such as coronary artery bypass surgery and coronary angioplasty, research indicates that mortality is lower at high volume hospitals compared to hospitals with low volumes.¹¹² In a recent article in the *Journal of the American Medical Association*,¹¹³ mortality rates for coronary artery bypass graft (CABG) surgery were higher in states without certificate-of-need (CON) regulation. CON preserves the

¹⁰⁹ Lucian L. Leape, Donald M. Berwick, and David W. Bates, "What Practices Will Most Improve Safety?" *JAMA*, 288(4), July 24/31, 2002.

¹¹⁰ *Ibid.*, p 504.

¹¹¹ *Ibid.*, p 507.

¹¹² R. Adams Dudley, Kirsten L. Johansen, Richard Brand, Deboarah J. Rennie, Arnold Milstein. "Selective Referral to High-Volume Hospitals," *JAMA*, 283(9), March 1, 2000.

¹¹³ Mary S. Vaughan-Sarrazin, Edward L. Hannan, Carol J. Gormley, Gary E. Rosenthal, "Mortality in Medicare Beneficiaries Following Coronary Artery Bypass Graft Surgery in States With and Without Certificate of Need Regulation," *JAMA*, 288 (15), October 16, 2002.

higher volume/higher quality relationship. It is estimated that referral to high volume hospitals for 10 high-risk procedures would prevent an estimated 4000 deaths annually nationwide.¹¹⁴

It has been suggested, however, that volume is not the only measure of quality outcomes, but that risk-adjusted mortality rates, complication rates, readmission rates, and length-of-stay are better indicators of quality than volume.¹¹⁵ Other arguments against the use of volume-based referrals include reduced competitiveness and an increase in procedures performed that may be unnecessary at those facilities that want to be recognized as high volume hospitals.¹¹⁶

Health Practitioner Staffing

The relationship between health practitioner staffing and quality of care and patient safety has received a great deal of attention recently, especially with respect to the current nurse staffing shortage. Physician staffing in the intensive care unit is one of The Leapfrog Group's three patient safety standards, as the use of intensivists and its effect on patient safety has been found to be positive.¹¹⁷ The shortage of nurses, however, has been a focus of national attention as the issue of staffing and its effect on patient safety is debated. Also, some groups have expressed concern regarding the quality and safety of care delivered by practitioners contracted from health care staffing agencies.

The American Hospital Association cites 126,000 vacant nursing positions currently in hospitals nationwide, and the aging of the nurse workforce is expected to create an additional shortage of 400,000 nurses by 2020. The JCAHO has analyzed data reported from their sentinel event database, noting that, in 24 percent of more than 1600 reported events, nurse staffing levels played a factor in the adverse event. The JCAHO Roundtable on the Nursing Shortage issued recommendations to reverse the trend in the nursing shortage: (1) create organizational cultures of retention; (2) bolster the nursing educational infrastructure; (3) establish financial incentives for investing in nursing; (4) establish "staffing levels based on nurse competency and skill mix relative to patient mix and acuity;" (5) increase funding for nurse education and the allocation of federal funds to health care organizations designated for nursing services.¹¹⁸

A U.S. Department of Health and Human Services study found a correlation between nurse staffing and increased rates of five adverse outcomes in medical patients - urinary tract infection, pneumonia, shock, upper gastrointestinal bleeding, and length of stay. A relationship was found between failure-to-rescue (a concept which refers to recognizing a potential for an adverse outcome and preventing it) and nurse staffing in major surgery patients. The study also found that the staffing of patient care units with registered nurses was associated with a 3 to 12 percent

¹¹⁴ The Leapfrog Group, Factsheet, Evidence-based Hospital Referral (EHR), November 2000.

¹¹⁵ *Ibid.*

¹¹⁶ *Ibid.*

¹¹⁷ Peter J. Pronovost, et. al., "Physician Staffing Patterns and Clinical Outcomes in Critically Ill Patients: A Systemic Review." *JAMA*, 288: 2151-2162. 2002, and Michael P. Young and John D. Birkmeyer, "Potential Reduction in Mortality Rates Using an Intensivist Model to Manage Intensive Care Units," *Effective Clinical Practice*, 3(6) Nov/Dec 2000.

¹¹⁸ The Joint Commission on Accreditation of Healthcare Organizations. Healthcare at the Crossroads: Strategies for Addressing the Evolving Nursing Crisis. November 2002.

reduction in the rates of the aforementioned outcomes. A reduction in these outcome rates of 2 to 25 percent was found with all types of nurses.¹¹⁹

In early 2002, the GAO was commissioned to study the possibility of a relationship between nurse staffing levels, quality of care, and expenditures. Data from three states (Mississippi, Ohio, and Washington) were analyzed and the results indicated that facilities which provided a higher number of nursing hours per resident day were “less likely to have repeated serious or potentially life-threatening quality problems, as measured by deficiencies detected during state surveys” than facilities with lower levels of nursing hours.¹²⁰ The effect seemed to be related specifically to the nursing hours since no relationship was found between spending per resident day and the number of deficiencies received by a facility.¹²¹

Another recently-released study analyzed the relationship between nursing staffing and patient outcomes in hospitals.¹²² For the study, a cross-section of nurses was surveyed regarding their demographics, work history, job satisfaction, and degree of job “burnout.” This information was then compared to patient outcomes data. It was determined that patients in hospitals with high patient to nurse ratios (fewer nurses per patient) experienced higher risk-adjusted 30-day mortality and failure-to-rescue rates.

The federal government requires nursing home facilities to follow certain nurse staffing requirements (enacted though the federal Nursing Home Report Act of 1997).¹²³ According to the National Citizens’ Coalition for Nursing Home Reform, the requirements are:

- A registered professional nurse is required to be on staff at least eight consecutive hours per day, seven days per week;
- 24-hour licensed nursing as necessary to meet the licensed nursing needs of residents; and
- Enough total nursing staff to meet the overall nursing needs of residents.¹²⁴

Nursing home facilities that accept Medicare and/or Medicaid payments must abide by these requirements. In Maryland, comprehensive care facilities (e.g., nursing homes) are required to have registered nurses (RNs) and nurse aides provide a minimum of two (2) hours of bedside care per licensed bed per day, seven (7) days per week.¹²⁵ The ratio of patients to nursing service personnel on duty to patients may not at any time be less than 25 to one. These facilities are

¹¹⁹ Jack Needleman, Peter I. Buerhaus, et al., Nurse Staffing and Patient Outcomes in Hospitals, Final Report, U.S. Dept. of Health and Human Services, HRSA, February 28, 2001

¹²⁰ General Accounting Office, Nursing Homes: Quality of Care More Related to Staffing than Spending, June 13, 2002.

¹²¹ Ibid.

¹²² Linda H. Aiken, Sean P. Clarke, Douglas M. Sloane, Julie Sochalski, Jeffrey H. Silber, “Hospital Nurse Staffing and Patient Mortality, Nurse Burnout, and Job Dissatisfaction,” JAMA 288.

¹²³ Nursing Home Reform Act, 42 U.S.C. 1302, 1395 et seq., part of the Omnibus Budget Reconciliation Act of 1987.

¹²⁴ National Citizens; Coalition for Nursing Home Reform, Nursing Home Staffing: A Guide for Residents, Families, Friends, and Caregivers.

¹²⁵ Although Maryland only requires two (2) hours of bedside care per day, Medicaid reimburses nursing facilities at levels above 3.5 hours per day. The majority of nursing homes staff above this level.

required to have a licensed RN on duty 24 hours a day to provide appropriate bedside care.¹²⁶ If the OHCQ conducts a survey and determines that staffing is not adequate, OHCQ has the authority to mandate a specified staffing pattern. In addition, nursing homes are required to post on each floor of the facility a notice that lists the current ratio of licensed personnel to residents and unlicensed personnel to residents.¹²⁷

In California, a mandatory patient-nurse ratio for hospitals was recently signed into law. It requires “licensed nurse-to-patient ratios by licensed nurse classification and by hospital unit for inpatient units in acute care hospitals.”¹²⁸ This law follows similar legislation enacted in 1977 that requires a nurse-patient ratio of 1:2 in intensive care and coronary care units, and also a requirement that at least half of the licensed nurses working in these units are registered nurses.¹²⁹ Proponents contend that more nurses per patient (or fewer patients per nurse) improve quality of care and patient safety, and also improve the working conditions for nurses. Opponents of the legislation argue that mandating a set ratio of nurses to patients increases costs associated with nurses’ salaries and may unintentionally cause those facilities that currently have ratios above the mandated minimum ratios to reduce their nursing staff, possibly because of the subsequent salary increases or due to a reduced supply of nurses. A study analyzing the costs of implementing the staffing mandate in California hospitals found that the increase in nursing expenditures range from approximately \$20,000 to over \$300,000.¹³⁰

A recommended alternative to mandated minimum staffing ratios are initiatives that take into consideration patient acuity or outcomes.¹³¹ Therefore, the allocation of nursing staff would be based on each hospital’s patient population, rather than a standard, generic ratio.

The Omnibus Budget Reconciliation Act of 1990 required the Secretary of the Department of Health and Human Services (HHS) to contract for a study to assess whether minimum-staffing ratios in nursing homes should be established. Although staffing thresholds were determined, the Secretary recommended at that time, that it was inappropriate to mandate staffing standards. As a result, the HHS found that that staffing standards “are insufficient for determining the appropriateness of staffing ratios...”¹³² These uncertainties over the reliability of staffing data and “feasibility of establishing staffing ratios” were cited as reasons that HHS would not recommend minimum staffing ratios for nursing homes. Because the studies do not address certain issues, such as the current nursing shortage and the importance of management and training of staff on the quality of care, the HHS found that it would be impractical to implement the recommended staffing thresholds.¹³³

¹²⁶ Code of Maryland Regulations, 10.07.02.12.

¹²⁷ Chapter 217 of 2000 (House Bill 747).

¹²⁸ California Assembly Bill 394 of 1999. Janet M. Coffman, Jean Ann Seago, and Joanne Spetz, “Minimum Nurse-to-Patient Ratios in Acute Care Hospitals in California,” *Health Affairs*, 21(5) 53-63: 2002.

¹²⁹ *Ibid.*

¹³⁰ *Ibid.*

¹³¹ *Ibid.*

¹³² Centers for Medicare and Medicaid Services, *Report to Congress: Appropriateness of Minimum Nurse Staffing Ratios in Nursing Homes: Phase II Final Report*. Letter to The Honorable Richard B. Cheney, President of the Senate, from Tommy G. Thompson, Secretary of the Department of Health and Human Services.

¹³³ *Ibid.*

Patient and Provider Education

Education of providers, caregivers and patients is believed to be an important means of improving patient safety within a health care environment. The proliferation of provider training and continuing education programs, which specifically address patient safety, demonstrates the importance the health care industry attaches to the reduction of medical errors. Continuing education in patient safety is an important method of educating health care providers.

It is believed that many errors could be curtailed through educating and empowering the consumer/patient to gain knowledge on the particular clinical subject area affecting that person and by asking questions. The federal Agency for Healthcare Research and Quality (AHRQ) is promoting a Patient Fact Sheet to assist consumers in becoming better informed about their illnesses and their care.¹³⁴ Because today's health care system is so complex, patients can benefit from becoming more involved in their own health care. (See Appendix J for AHRQ's *20 Tips to Help Prevent Medical Errors*).

~~(b)~~

C. Regulatory

In 1986, the Maryland General Assembly passed a law that required all Maryland hospitals to have Risk Management Plans and Programs. These programs focused on the internal hospital systems to identify and evaluate quality of care incidents and to prevent reoccurrence. Two other legislatively mandated programs complemented the risk management requirements. The Utilization Review Statute and Regulations required hospitals to monitor utilization and quality of care within the hospital and to provide an annual report on these activities to the Department. The Physician Credentialing Statute required hospitals to use the risk management and utilization review data on a biennial basis to evaluate physician performance. In 1988, when these three sets of regulations were implemented, Maryland was recognized as a leader in the patient safety and performance improvement areas.

Since 1988, the JCAHO has altered its physician credentialing standards and has also established patient safety standards. The JCAHO has also encouraged the reporting of serious adverse events (sentinel events) and has required hospitals to conduct a specific type of evaluation (root cause analysis) when a serious adverse event occurs. In addition, the National Quality Forum, a consensus organization of more than 100 provider, consumer, and advocacy groups, evaluated and released a comprehensive report detailing a minimum of 27 serious adverse events that should be reported by all licensed health care facilities. Based on these new standards, many states, particularly since release of the 1999 IOM report, have begun to look at their own patient safety initiatives and to establish new standards.

To evaluate the current state of patient safety activities across the nation, the Maryland Patient Safety Coalition reviewed a number of activities that were ongoing in other states. These included presentations from representatives of New York, Massachusetts, and Pennsylvania as well as printed materials from other states. Currently 20 states have mandatory reporting systems for adverse events. These systems range from requirements to report any and all events to

¹³⁴ AHRQ. www.ahrq.gov/consumer/20tips.htm.

requirements for reporting only the most serious adverse events. In some states, the reports are public; in others, the reports are held confidential.

In the fall of 2001, DHMH evaluated hospital patient safety activities in Maryland. The Office of Health Care Quality asked all hospitals to update and resubmit their Risk Management/Patient Safety Plans. Hospitals were also asked to submit any other relevant materials, particularly those that pertained to patient safety. All of the 47 acute hospitals responded. According to OHCQ, an analysis of the information received demonstrated that:

- Risk Management Plans were fragmented. In many cases, there was a Risk Management Plan to meet state regulations, a separate plan to meet JCAHO Standards, and yet another plan to reflect current practice.
- Language within hospitals was inconsistent. Within a single hospital, an “event” could be called or labeled a variety of terms including an “incident”, an “occurrence”, a “sentinel event”, or an “adverse outcome.” Although the definitions of each of these may be equivalent, it was possible to have a completely separate reporting and evaluation mechanism to address the adverse event depending on what it was called.
- There was little categorization of events into levels of harm as required by JCAHO. For example, a medication overdose that resulted in death of a patient was classified the same as a medication error that had no bad outcome.
- Internal reporting by staff was passive. Rather than active statements indicating who, what, how, and when occurrences must be reported, most plans stated, “An adverse outcome shall be reported to the risk manager...”
- Only a few of the plans included a procedure for adverse event notification to the patient or family.
- In many hospitals, the sentinel event policy was verbatim from JCAHO standards and was limited to rape, infant abduction, blood transfusion reaction, wrong side surgery, or suicide. Hospitals had not considered the frequency or types of occurrences unique to the types of services delivered and adjusted the patient safety program accordingly.
- In many cases, the Risk Management/Patient Safety program administratively reports to the Chief Financial Officer indicating that the focus of the program is liability reduction rather than patient safety.

OHCQ also evaluated a series of complaints that had been received by the Department to determine frequency of reporting to JCAHO, particularly events that could be considered “sentinel” and that would fit the JCAHO reporting policy. OHCQ found that few events were reported to JCAHO and that these were frequently limited to those events that were likely to become public.

It should be noted that the number of hospital complaints filed with the OHCQ has increased significantly. In FY00, OHCQ received 182 complaints; in FY01, 233; and, in FY02, 351. The seriousness of the complaints has also increased. Examples of complaints that have been investigated and verified include:

- A three-year-old child was given an overdose of chemotherapy and lost his hearing. A reporter from *The Baltimore Sun* notified OHCQ.

- A 76-year-old woman had a breast removed. There was no evidence of cancer. The hospital investigated and determined that error was due to a misfiled biopsy report from a diagnostic center. Hospital reported to OHCQ.
- Two patients died of cement embolism following vertebroplasty procedures. The same physician conducted the procedures on the same day. Hospital staff anonymously reported to OHCQ.
- A patient was given overdose of haloperidol and died. Family notified OHCQ.
- A pregnant woman with a known allergy to cephalosporins was given Rocephin and subsequently miscarried. The family of the patient notified OHCQ.
- A patient with history of heart problems was discharged from emergency room before the doctor read the EKG and echocardiogram. Patient had a myocardial infarction and is in a vegetative state. Family notified OHCQ.
- A patient with vaginal bleeding was accidentally injected with 10 cc. of air during IV preparation. Patient was sent to Shock Trauma for treatment in hyperbaric chamber. Medicaid notified OHCQ.
- A nursing assistant accidentally pulled tracheotomy tube from patient while turning and positioning her. Patient is in permanent vegetative state. Hospital employee notified OHCQ.

Currently, the Department only collects information on adverse event reports as a consequence of complaints received, voluntary reports from hospitals, or notification from JCAHO. OHCQ reports that some hospitals, although not required, have chosen to report serious adverse events to OHCQ. Unless there has been a public complaint, OHCQ has treated these cases as peer review information and has kept the information confidential.

Currently regulations pertaining to nursing facilities require cases of resident abuse and neglect to be reported to OCHQ, a law enforcement agency, or the Maryland Office on Aging. A nursing facility is required to thoroughly investigate all allegations of abuse and neglect.

The Interim Report recommended an evaluation of the Risk Management regulations for two purposes:

- To increase accountability within the hospital through better identification, reporting, and evaluation of events; and
- To increase external accountability through mandatory reporting of a serious events and its evaluation to OHCQ for its review and analysis.

Under the direction of Carol Benner, Director of OHCQ, a subcommittee was formed to review and evaluate the Risk Management Regulations. The workgroup included representatives of the Maryland Hospital Association, malpractice carriers, a number of hospitals, and the Maryland Society for Healthcare Risk Management as well as the Assistant Attorney General representing OHCQ (see Appendix F). Meetings were lengthy, lively, and included much give and take and compromise. In addition, regular reports were provided to the Maryland Patient Safety Coalition for additional review and comment. Several drafts of the proposed regulations were prepared and discussed. The draft of proposed regulations was also posted on the OHCQ website for additional review and comment (see Appendix K). As of December 1, 2002, the regulations

have also been shared with the Plaintiffs' and Defense Sections of the Maryland Bar Association, the JCAHO, the National Academy for State Health Policy and others for comment.

Proposed changes to the existing regulations were based on recommendations from the 1999 IOM study *To Err is Human*, JCAHO Accreditation Standards for Hospitals, the Department of Veterans Affairs Patient Safety program, and the National Quality Forum's *Consensus Report of Serious Reportable Events*. In general, the proposed changes accomplish the following:

- Define and categorize events based on actual occurrence and severity;
- Require internal reporting of certain events;
- Encourage reporting of near-misses;
- Specify the type of response to serious adverse events and near-misses;
- Define root cause analysis (RCA) and require an RCA for certain events;
- Emphasize that Maryland law provides for protection of event information (confidentiality and non-discoverability) under certain conditions;
- Require reporting of only those events that result in death or serious disability to the Department and provide for confidentiality protections;
- Require notification to a patient and, when appropriate, that patient's family of an outcome of care that differs significantly from an anticipated outcome;
- Require the hospital to provide notice to a patient and family that complaints can be filed with the Department; and
- Generally update language to be consistent with JCAHO terminology.

The proposed regulations are a cautious approach to the issue of patient safety that the Coalition believes is appropriate and responsible. The emphasis is on the hospital's own internal ability to identify errors and devise possible solutions to prevent reoccurrence. Mandatory reporting is important, but is limited. Unlike other states, only the most serious events, those resulting in death or serious disability (significant mental or physical impairment lasting more than 7 days) are reported. In addition, the hospital must also submit its evaluation or root cause analysis. Many hospitals have already begun to self-report and have found technical assistance provided by the Department to be helpful.

As of mid-December, there has been general consensus on the proposed regulations by the Health Department and the representatives of the Maryland Hospital Association. The Department is required by law to seek consultation from other groups, including the Maryland Defense and Plaintiffs' Bars, the Medical and Chirurgical Society, and advocates. The regulations, as presented in Appendix K, have been sent to these groups for comment. Once these comments are received, the Department will move forward to promulgate the regulations. The expected implementation date is delayed to allow for adequate education of hospital staff, but is anticipated to occur in the fall of 2003.

The confidentiality of materials, both within the hospital setting and those that are submitted to the OHCQ, is currently provided under statute. The Attorney General's Office has verified that, unlike many other states, Maryland does provide adequate protections to both encourage frank and open evaluation and to prevent release of peer review materials for the purpose of civil litigation. The cost to hospitals to conduct the activities as defined in the revised

regulations should be minimal because of JCAHO's current sentinel event reporting and analysis policy.

The Maryland Patient Safety Coalition, the Maryland Health Care Commission, and the Department are hopeful that, once again, the proposed patient safety regulations will serve as a model for the nation.

IV. Conclusion and Recommendations

Assuring patient safety is an ongoing concern, however recognizing the issue exists, openly discussing, and systematically analyzing adverse events and near misses, and sharing this information is an important first step.

In 2001, the Maryland General Assembly charged the Maryland Health Care Commission (MHCC), in cooperation with the Department of Health and Mental Hygiene (DHMH), with studying the feasibility of developing a system for reducing the incidence of preventable adverse medical events in Maryland, including but not limited to a system of reporting such incidents. The recommendations for the design of a patient safety system in Maryland are built upon the proposed suggestions in the Interim Report, issued in 2002.

Developing a ‘patient safety system’ for a medical facility, let alone an entire state, is a daunting task. Other states have passed patient safety initiatives piecemeal rather than taking a comprehensive approach. For example, twenty states have opted for mandatory reporting of certain adverse events, while others have instituted laws regulating health care professionals (California’s nursing staff ratios and New York’s restrictions on hours worked by residents). Employers (e.g., Leapfrog Group) have also been involved in patient safety efforts using selective contracting to promote safe practices that are often seen as cost effective in the long run. While all of these initiatives are notable, a comprehensive initiative promoting a common philosophical approach to the issues related to patient safety has been missing in most state efforts.

The recommendations detailed below attempt to establish a common philosophical approach for Maryland initiatives. This approach, similar to the VA and aviation industry, emphasizes the creation of a culture which is attentive to issues of patient safety, encourages and rewards (or at least does not punish) those who bring adverse events and near misses to the attention of leadership for investigation. It promotes the use of Root Cause Analysis as a tool for the evaluation of errors or potential errors and fosters systems changes, which may prevent other similar errors. The approach outlined in this report does not address intentionally unsafe acts, which are within the purview of the existing health occupation boards. Instead, the focus is on improving the entire system of health care delivery, based on evidence that indicates that the majority of errors are due to system failures.

In order to develop final recommendations on Maryland’s patient safety initiatives, the MHCC explored several global issues. Input on these issues was elicited from the Maryland Patient Safety Coalition as well as national experts. Several questions formed the basis for the Coalition’s deliberations:

1. Should the patient safety system focus on accountability, quality improvement, or both (i.e., should the system be punitive or nonpunitive in emphasis)?
2. Should the patient safety reporting system be voluntary or mandatory or include elements of both approaches?
3. Should information collected be protected from legal discovery to be used for quality improvement or should it be made public for consumer accountability?

Based on information obtained from national leaders in health care and patient safety, a thorough literature review, and feedback from members of the Maryland Patient Safety Coalition, the Commission recommends that the Maryland patient safety system be based on a three-pronged approach which includes: (1) the establishment of the Maryland Patient Safety Center; (2) the use of the State's regulatory authority to promote systems improvements; and (3) limited mandatory reporting (see Diagram A).

Essential to the success of this model is the creation of a system that focuses on quality improvement, encourages voluntary reporting without fear of blame or reprisal, and protects against legal discovery. While the focus of this report is centered around the patient safety activities and initiatives of hospitals and nursing homes, the ultimate goal is to involve all health care facilities (including ambulatory surgery centers and assisted living facilities) in a comprehensive, systemic effort to improve patient safety and provide high quality health care.

- I. **Develop Maryland Patient Safety Center (MPSC)** - The Maryland Patient Safety Center should form the foundation of the patient safety effort. The MPSC will provide an institution at the state level similar to the national patient safety center recommended in the 1999 IOM report. Its purpose is to provide a means to share information between facilities without fear of reprisal and to exchange ideas about how to address adverse events and improve processes of care (see Diagram B).
- The MPSC should serve as the data repository center for voluntarily reported adverse events and near misses and as the primary coordinator for educational activities related to building consensus around patient safety issues.
 - Support for the MPSC and its activities will be developed through a grassroots effort to build consensus around patient safety initiatives. An Advisory Board, comprised of representatives from health care industry associations, health care professional societies and associations, the Medicare Quality Improvement Organization (The Delmarva Foundation), the Maryland Health Care Commission (MHCC), and other interested groups, will encourage health care professionals and facilities to participate in the voluntary reporting and educational activities of the Center.
 - Legislation should be introduced in the 2003 General Assembly Session amending the Maryland statute to include the MPSC under the definition of a medical review committee, so that reports will be protected from discovery. Existing reporting protections for civil immunity that are available to all health care professionals reporting to all health occupation boards and medical review committees should be granted to those who report to the MPSC.
 - The MPSC should be incorporated within a non-regulatory body to establish trust with facilities and providers to encourage reporting. In fact, there should be a "firewall" between the licensing and investigating functions of DHMH and voluntary reporting to the MPSC.

- Financial resources to establish a MPSC need to be considered. After consultation with the sponsor of the enabling patient safety legislation, the MHCC supported an application by the University of Maryland's Organized Research Center on Health Policy to the federal Agency for Healthcare Research and Quality (AHRQ) to fund the development of MPSC for a three-year period at \$500,000 per year. This grant, if awarded, will provide funding to establish a Center. It will also provide an opportunity to test whether a grassroots consensus building approach can make a voluntary system of reporting work statewide. Initial reporting will be limited to hospitals and nursing homes. If the AHRQ grant is not funded, the State should pursue other grants from private foundations.

II. **Promote Data Systems and Advanced Technologies** – State regulatory agencies should give priority to patient safety initiatives that improve the system of delivering health care.

- The literature indicates that most adverse events are attributable to systems of care, not the individual practitioners committing an intentionally unsafe act.
- Several initiatives have proven effective and have been recommended to reduce the occurrence of adverse events and improve patient safety. Technologically-advanced and/or resource intensive practices shown to be effective in reducing the occurrence of adverse events should be adopted by facilities. They include computerized physician order entry (CPOE), bar coding, and the use of intensivists in intensive care units.
- Two state agencies, the Health Services Cost Review Commission (HSCRC) and the Maryland Health Care Commission (MHCC) have the opportunity to give priority to patient safety in their regulatory decisions.
 - HSCRC – The HSCRC approves hospital rates in the State. Research indicates major systems initiatives such as CPOE can vary in cost per hospital depending on the size of the hospital. Currently, at least twelve of Maryland's forty-seven acute care hospitals have some level of CPOE or are in the process of implementing it (according to the Maryland Patient Safety Coalition survey). Some hospitals are implementing CPOE in stages to spread the costs. Subject to the requirements of the HSCRC, facilities should have the opportunity to request an increase in rates based on the capital expenditures associated with introduction of advanced technologies such as electronic medical records and CPOE that have been linked with patient safety improvements. The HSCRC should consider whether these initiatives will be cost-neutral in the long run by creating greater efficiency and decreasing length of stay due to complications and reducing malpractice liability costs.
 - MHCC – The MHCC has at least two vehicles that should be used to prioritize safety issues:
 - 1) Performance Evaluation Guides – These Guides should inform consumers regarding technologies available to improve patient safety and facilities that have implemented them. This would inform the consumer's selection process. For example, the Guide could indicate the presence or absence of bar coding, electronic

medical records or CPOE at a particular facility. The Guides could also indicate whether a hospital or nursing home had contracted to participate in reporting to the proposed Maryland Patient Safety Center.

2) State Health Plan and Certificate of Need Process – The MHCC should incorporate approval standards into the State Health Plan that give priority to projects designed to improve patient safety. This would provide guidance in Certificate of Need reviews for new projects.

The MHCC has already incorporated certain evidence based practices into the Plan Chapter on Specialized Cardiac Services – Cardiac Surgery and Therapeutic Catherization Services (COMAR 10.24.17) which set minimum volume standards for programs doing open heart surgery and angioplasty.

- Initiatives requiring minimal resources should be encouraged to be implemented in a relatively short period of time. They include those listed on pages 36 to 40 of this report.

III. **Implement Strengthened Hospital Patient Safety Programs and Limited Mandatory Reporting to the Department** - The proposed regulations were developed in consultation with the Maryland Hospital Association, malpractice carriers, a number of hospital representatives, and the Maryland Society for Healthcare Risk Management as well as the Assistant Attorney General representing OHCQ.

- Risk Management regulations should be revised to strengthen hospital Patient Safety Programs, specifically the setting of standards for reporting of adverse events and near-misses, performance of root cause analysis, and other evaluations and trending of events and near-misses to identify patterns. Since 1988, Maryland has had risk management regulations that have required some internal incident and evaluation procedure; however, these need to be strengthened and revised.
- Regulations need to be implemented to increase external and public accountability. Those events that result in death or serious disability should be reported to the Department with the corresponding root cause analysis. The Department should review the event and the root cause analysis to ensure that the hospital has responded appropriately. The root cause analysis and any medical review committee information should remain confidential and non-disclosable. Only deficiencies resulting from a complaint investigation would be publicly available.
- The proposed regulatory changes, based on recommendations from the 1999 IOM study *To Err is Human*, JCAHO Accreditation Standards for Hospitals, the Department of Veterans Affairs Patient Safety program, and the National Quality Forum's *Consensus Report of Serious Reportable Events*, are intended to accomplish the following:
 - Define and categorize events based on actual occurrence and severity;
 - Require internal reporting of certain events;
 - Encourage reporting of near-misses;

- Specify the type of response to serious adverse events and near-misses;
 - Define root cause analysis (RCA) and require an RCA for certain events;
 - Emphasize that Maryland law provides for protection of event information (confidentiality and non-discoverability) under certain conditions;
 - Require reporting of only those events that result in death or serious disability to the Department and provide for confidentiality protections;
 - Require notification to a patient and, when appropriate, that patient's family of an outcome of care that differs significantly from an anticipated outcome;
 - Require the hospital to provide notice to a patient and family that complaints can be filed with the Department; and
 - Generally update language to be consistent with JCAHO terminology.
- Regulations should be promulgated in the near future to require such reporting by other types of health care providers, such as nursing facilities and ambulatory care centers.

IV. **Other Issues**

- Nurse Staff Ratios – State should continue to monitor ongoing research.

The MHCC reviewed literature on nursing staff ratios and other quality assurance initiatives and concluded that workforce mandates and their consequences are not conclusive. In Maryland, minimum nursing personnel staffing levels of bedside care for comprehensive care facilities are required by regulations. Also, OHCQ maintains the authority to issue staffing levels for hospitals, if necessary. While higher nurse-to-patient ratios have been shown to improve outcomes, there is still debate about impact of requiring specific ratios on the health care system as a whole with respect to health care costs, access to care, and manpower shortages. For that reason, the MHCC declines to endorse mandatory ratios for hospitals at this time and instead recommends monitoring outcomes in states that do mandate ratios. Consideration should also be given to the appropriateness of ratios given the level of patient's acuity and whether the ratios apply to actual bedside time.

- Maryland Patient Safety Coalition – The Patient Safety Coalition should continue as an effort to provide leadership and expertise in addressing patient safety issues.

Ongoing meetings with leaders of Maryland facilities, State Boards of Health Occupations, and professional societies and associations will foster and promote a commitment to improving the quality of health care and patient safety.

- The Maryland Health Care Commission – MHCC should continue to monitor evolving patient safety initiatives.

The MHCC should watch developments that are being implemented by other states as well as any national initiatives including Congressional requirements as well as programs

undertaken by the Department of Veterans Affairs and the Agency for Healthcare Research and Quality.

The MHCC should have a role in the development of the proposed three-pronged approach to patient safety in Maryland and should periodically review the progress of the proposed effort.

- Future patient safety activities in Maryland should be done in collaboration with national initiatives (such as the NQF and JCAHO).

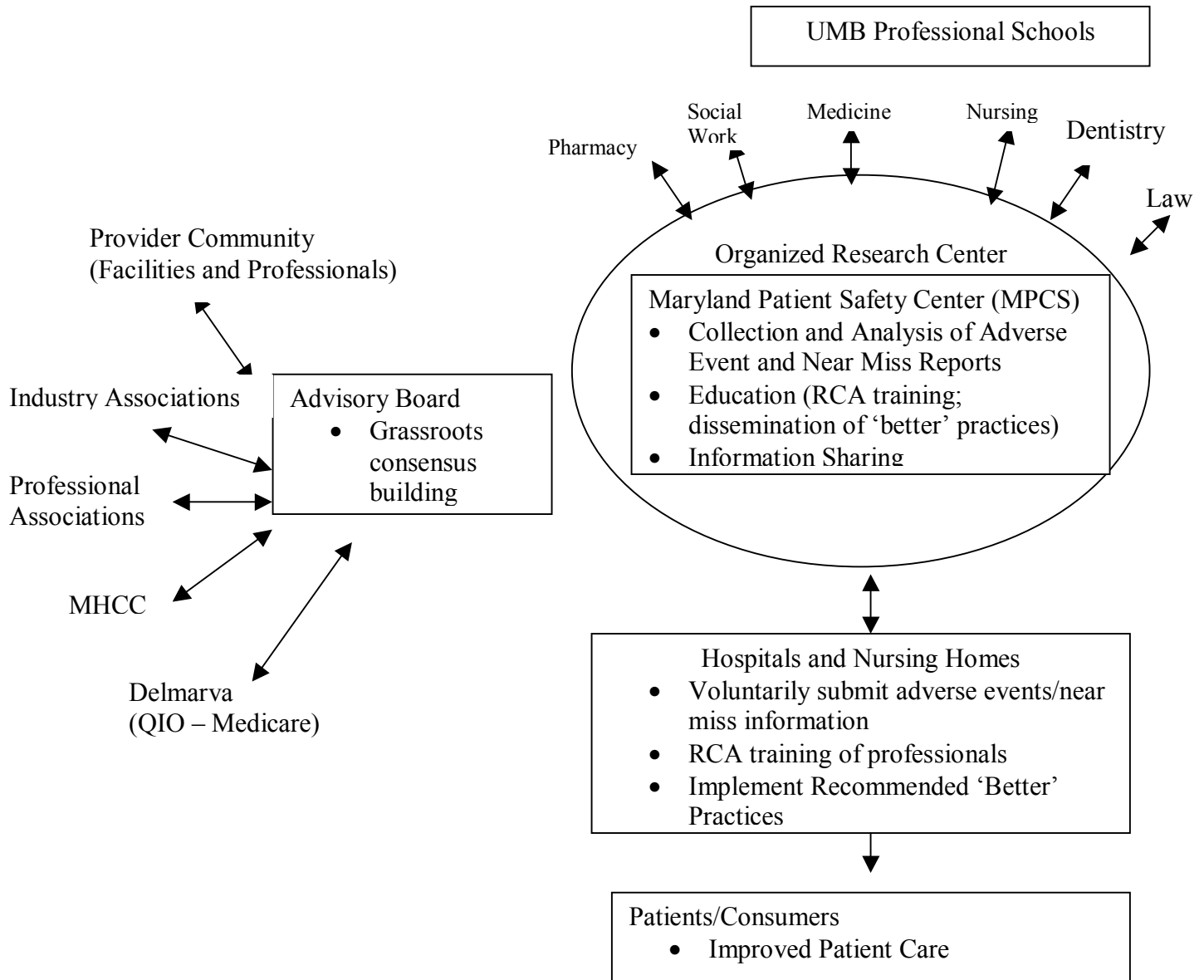
Diagram A

Maryland's Patient Safety Strategy A Three-Pronged Approach

<i>Objective</i>	Strengthening of Hospital Patient Safety Program and Limited Mandatory Reporting – limited to adverse events resulting in death or serious disability	Promote Data Systems and Advanced Technologies to improve care	Promote Voluntary Reporting of De-identified Information on all Adverse Events and Near Misses and Provider Education
<i>Implementing Agency</i>	Department of Health and Mental Hygiene	Maryland Health Care Commission – Certificate of Need Program (CON), Hospital and Nursing Home Report Cards Health Services Cost Review Commission – hospital rate allowances for technological improvement	Maryland Patient Safety Center - UMB
<i>Affected Entity</i>	Hospitals and potentially other licensed facilities	All facilities regulated by CON and hospitals that are rate regulated	Hospitals, Nursing Homes, and potentially all facilities

Diagram B

**Linkages of the Maryland Patient Safety Center
Demonstration Project**



Selected Bibliography

Aiken, L., S.P. Clarke, D.M. Sloane, J. Sochalski, and J. H. Silber, "Hospital Nurse Staffing and Patient Mortality, Nurse Burnout, and Job Dissatisfaction," JAMA. 288(16): October 23/30, 2002.

Agency for Healthcare Research and Quality, Making Health Care Safer: A Critical Analysis of Patient Safety Practices, July 20, 2001.

Agency for Healthcare Research and Quality, Press Release, "Reducing and Preventing Adverse Drug Events Decreases Hospital Costs." Press Release, April 11, 2001,
<http://www.ahrq.gov/news/press/pr2001/adepr.htm>

American Hospital Association, AHA Guide to Computerized Physician Order-Entry Systems, November 2000.

Bagian, JP, Lee, C., Gosbee, J., DeRosier, J., Stalhandske, E., Eldridge, N., Williams, MB.
"Developing and Deploying a Patient Safety Program in a Large Health Care System: You Can't Fix What You Don't Know." The Joint Commission Journal on Quality Improvement, 27(10), October 2001.

"Bar Coding for Patient Safety" Advocacy White Paper, Healthcare Information and Management System Society. 12/27/01.

Barron, J. Case Study: Veterans Health Administration. Risk Management Foundation of the Harvard Medical Institutions. 2002, (pp 140-144).

Bates, D.W. "Using Information Technology to Reduce Rates of Medication Errors in Hospitals," British Medical Journal, March 18, 2000; 320.

Birkmeyer, J.D., et. al. Leapfrog Patient Safety Standards: The Potential Benefits of Universal Adoption. November 2000.

Birkmeyer, J.D.,. Economic Implications of the Leapfrog Safety Standards. June 2001.

California HealthCare Foundation, First Consulting Group, "A Primer on Physician Order Entry" Sept. 2000.

Centers for Medicare and Medicaid Services, Report to Congress: Appropriateness of Minimum Nurse Staffing Ratios in Nursing Homes: Phase II Final Report. Letter to The Honorable Richard B. Cheney, President of the Senate, from Tommy G. Thompson, Secretary of the Department of Health and Human Services.

Coffman, J.M., J.A. Seago, and J. Spetz, "Minimum Nurse-to-Patient Ratios in Acute Care Hospitals in California," Health Affairs, 21(5) 53-63: 2002.

Committee on Quality of Health Care in America, Institute of Medicine. Crossing the Quality Chasm: A New Health System for the 21st Century. National Academy of Sciences, 2001.

Department of Veterans Affairs, Veterans Health Administration, VHA Handbook 1050.1. January 30, 2002.

DeRosier, J., E. Stalhandske, J.P. Bagian, and T. Nudell. "Using Health Care Failure Mode and Effect Analysis™: The VA National Center for Patient Safety's Prospective Risk Analysis System." The Joint Commission Journal on Quality Improvement, May 2002.

Dudley, R.A., K. L. Johansen, R. Brand, D.J. Rennie, A. Milstein. "Selective Referral to High-Volume Hospitals," JAMA, 283(9), March 1, 2000.

Eldridge, N., Presentation to the Office of Quality and Performance. The Department of Veterans Affairs National Center for Patient Safety. January 29, 2002.

Freudenheim, M., "Companies Start Fund to Reward Hospitals for Better Care." The New York Times. October 18, 2001.

General Accounting Office, Nursing Homes: Quality of Care More Related to Staffing than Spending, June 13, 2002.

George, D.L., M.F. Emons, K.M. Uchida, and J. Kosecoff, "The Challenge of Assessing Patient Safety in America's Hospitals." Protocare Sciences, January 15, 2002.

Heimrich, R.L., PhD, Professor Psychology at the University of Texas at Austin. Presentation to the National Patient Safety Foundation conference "Patient Safety: Let's Get Practical", Indianapolis, IN, April 22-24, 2002.

ISMP Medication Safety Alert. "What's in a Name? Ways to Prevent Dispensing Errors Linked to Name Confusion." June 12, 2002. <http://www.ismp.org/MSAarticles/NamePrint.htm>.

Johnson, C. R. Carlson, C. Tucker, and C. Willette. "Using BCMA Software to Improve Patient Safety in Veterans Administration Medical Centers," Journal of Health Care Information Management, 16(1). Winter 2002.

The Joint Commission on Accreditation of Healthcare Organizations. Healthcare at the Crossroads: Strategies for Addressing the Evolving Nursing Crisis. November 2002. <http://www.jcaho.org>.

Kilbridge, P., E. Welebob, and D. Classen, "Overview of the Leapfrog Group Evaluation Tool for Computerized Physician Order Entry," Report by the First Consulting Group for the Leapfrog Group. December 2001.

Kohn, LT, Corrigan, JM, Donaldson, MS, eds., Institute of Medicine. To Err is Human: Building a Safer Health System. National Academy of Sciences. 2000.

Kimmel, K.C., and J.Sensmeier, "A Technological Approach to Enhancing Patient Safety," Healthcare Information and Management Systems Society, 2002.

Leape, L., D Berwick, and D Bates, "What Practices Will Most Improve Safety?" JAMA, 288(4): July 24/31, 2002.

Leape, L., D. Woods, M. J. Hatlie, K.W. Kizer, S.A. Schroeder, and G.D. Lundberg. "Promoting Patient Safety by Preventing Medical Error," JAMA 280(16): Oct 28, 1998.

Leape, L., David J. Cullen, Margaret Dempsey Clapp, Elisabeth Burdick, Harold J. Demonaco, Jeanette Ives Erickson, and David W. Bates, "Pharmacist Participation on Physician Rounds and Adverse Drug Events in the Intensive Care Unit," JAMA, 282(3), July 21, 1999.

The Leapfrog Group, <http://www.leapfroggroup.org/>.

Luciano, L. "Government Health System Leads the Way." Reducing Medical Errors and Improving Patient Safety: Success Stories from the Front Lines. The Institute for Healthcare Improvement and The National Coalition on Healthcare. February 2000.

"Medication Safety Issue Brief: Using Automation to Reduce Errors," Joint project of the American Hospital Association, the American Society of Health-System Pharmacists and Hospitals & Health Networks.

Metzger, J. and F. Turisco, "Computerized Physician Order Entry: A Look at the Vendor Marketplace and Getting Started," Report by the First Consulting Group for the Leapfrog Group, December 2001. <http://www.leapfroggroup.org/CPOE/CPOE%20Guide.pdf>

Miller, L.K., M.S. Nelson, B.W. Spurlock, "A Compendium of Suggested Practices for Preventing and Reducing Medication Errors," The California Institute for Health Systems Performance, November 2001.

Morris, A.H., "Decision support and safety of clinical environments," Quality and Safety in Health Care 11, pp. 69-75, 2002.

National Quality Forum (NQF), "Safe Practices" in Hospital Care. NQF Project Summary, <http://www.qualityforum.org>

National Citizens; Coalition for Nursing Home Reform, Nursing Home Staffing: A Guide for Residents, Families, Friends, and Caregivers.

Needleman, J., P.I. Buerhaus, S. Mattke, M. Stewart, and K. Zelevinsky. Nurse Staffing and Patient Outcomes in Hospitals, Final Report, U.S. Dept. of Health and Human Services, HRSA, February 28, 2001

Pronovost, P., H. Waters, and T. Dorman, "Intensive Care Unit Physician Staffing," Leapfrog Patient Safety Standards – Economic Implications, John D. Birkmeyer, M.D., Research Director and Editor. June 2001.

Pronovost, P.J., D.C. Angus, T. Dorman, K.A. Robinson, T.T. Dremsizov, and T.L. Young, "Physician Staffing Patterns and Clinical Outcomes in Critically Ill Patients: A Systemic Review." JAMA, 288: 2151-2162. 2002.

Raschke, R.A., B. Gollihare, T.A. Wunderlich, J.R. Guidry, A.I. Leibowitz, J.C. Peirce, L. Lemelson, M.A. Heisler, and C. Susong. "A Computer Alert System to Prevent Injury from Adverse Drug Events." JAMA. 280(15): October 21 1998.

Robinet, J.E., "Pittsburgh's Health Care Initiative in National Spotlight." Pittsburgh Business Times, <http://pittsburgh.bcentral.com>. May 31, 2001.

Rosenthal, J., M. Booth, and A. Barry. "Cost Implications of State Medical Error Reporting Programs: A Briefing Paper." National Academy for State Health Policy. May 2001.

Rosenthal, J., T. Riley, and M. Booth, National Academy for State Health Policy, State Reporting of Medical Errors and Adverse Events: Results of a 50-State Survey, April 2000.

Sarudi, D., "The Leapfrog Effect," Hospital and Health Networks, 75(5), May 2001.

Scalise, D., "CPOE, An Executive's Guide," Hospital and Health Networks, 76(6), June 2002.

Segel, K.T., "A New Model for Healthcare Delivery." <http://www.smc.org>. July/August 2001.

Shojania, K.G., Clinician-Researcher, University of California, San Francisco, "Important Practical Limitations for Decision Support." Letter to the Editor, British Medical Journal. August 5, 2002.

Shojania, K.G., B.W. Duncan, K.M. McDonald, et al., eds. Making Health Care Safer: A Critical Analysis of Patient Safety Practices. Evidence Report/Technology Assessment No. 43 (Prepared by the University of California at San Francisco-Stanford Evidence -based Practice Center under Contract No 290-97-0013), AHRQ Publication No. 01-E058, Rockville, MD: Agency for Healthcare Research and Quality. July 2001.

Solovy, A. "At Leadership Forum, Hospital Execs Brainstorm Approaches to Patient Safety," Hospitals & Health Networks, April 2001.

Teich, J.M., J.P. Glaser, R.F. Beckley, M. Aranow, D.W. Bates, G.J. Kuperman, et al. "Toward cost-effective, quality care; the Brigham Integrated Computing System" Proc 2nd Nicholas E. Davies CPR Recognition Symposium. Washington DC: Computerized Patient Record Institute. 1996; pp. 3-34.

W.M. Tierney, M.E. Miller, J.M. Overhage, and CJ McDonald, "Physician inpatient order writing on microcomputer workstations. Effects on resource utilization," Journal of the American Medical Association 269(1993):379-383.

U.S. Pharmacopeia, <http://www.usp.org/>.

The Veterans Administration. "VA to Develop No-Penalty, Medical Error Reporting System." *Veterans Health Administration Highlights*. Health Benefits and Services. June 2, 2000. <http://www.va.gov>.

The Veterans Administration. "Veterans' National Center for Patient Safety is a Finalist in Prestigious American Government Award." *Veterans Health Administration Highlights*, Health Benefits and Services. .September 7, 2001. <http://www.va.gov>.

The Veterans Health Administration National Patient Safety Improvement Handbook. Department of Veterans Affairs, VHA Handbook 1050.1. January 30, 2002.

Woods, D., Studies in Human Factors as cited in an untitled document from Ohio State University at <http://www.osu.edu/units/research/archive/techmed.htm>

Vaughan-Sarrazin, M.S., E.L. Hannan, C.J. Gormley, G.E. Rosenthal, "Mortality in Medicare Beneficiaries Following Coronary Artery Bypass Graft Surgery in States With and Without Certificate of Need Regulation," JAMA, 288 (15), October 16, 2002

Young, M. and J Birkmeyer, "Potential Reduction in Mortality Rates Using an Intensivist Model to Manage Intensive Care Units," Effective Clinical Practice, Nov/Dec 2000, 3(6).